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Medical errors kill many Americans each year. Information on sentinel events gathered at military hospitals is typically presented as numerator data without much analysis. Fearing litigation and blame, health care providers appear to be reluctant to report on "near misses" where errors have occurred, but not resulted in actual harm. Using a non-punitive approach, anesthesiologists championed a method to learn from errors in order to improve patient outcomes. This graduate management project involves analysis of trends and error rates in the risk management database of Winn Army Community Hospital. Numbers of incident reports were compared before and after educational interventions to increase voluntary reporting. Numbers of prescription edits were quantified and compared before and after default prescriptions were introduced to decrease errors. Recommendations were made about efforts which may best serve an effective error reduction initiative.

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An Error Reduction Initiative

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U.S. Army-Baylor University
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Abstract

Medical errors kill many Americans each year. Information on sentinel events gathered at military hospitals is typically presented as numerator data without much analysis. Fearing litigation and blame, health care providers appear to be reluctant to report on "near misses" where errors have occurred, but not resulted in actual harm. Using a non-punitive approach, anesthesiologists championed a method to learn from errors in order to improve patient outcomes. This graduate management project involves analysis of trends and error rates in the risk management database of Winn Army Community Hospital. Numbers of incident reports were compared before and after educational interventions to increase voluntary reporting. Numbers of prescription edits were quantified and compared before and after default prescriptions were introduced to decrease errors. Recommendations were made about efforts which may best serve an effective error reduction initiative.

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Introduction

People who are ill seek physicians who are going to listen to, examine, treat and ultimately cure them. No one likes to think that his physician will make a mistake. It is very uncomfortable to entertain the morbid thought that one may literally lose his life by entering a hospital. The subjects of medicine and healthcare do not immediately conjure up the idea of errors. Perhaps the long-standing myth of the power and mystique of physicians makes it unseemly at best and unconscionable at worst to broach the subject of medical errors. The study of errors in medicine has been fraught with difficulty secondary to the nature of the subject material. In some cases, incidents that occur as a result of errors are fatal. Is has been said, sardonically, that doctors have literally and figuratively "buried" their mistakes. Not only have patients been reluctant to think about medical errors, but also physicians, themselves, have felt that they must be infallible. However, this is an unreasonable expectation for any group of human beings. Mistakes are part of being human. Mistakes will invariably be made (Bosk, 1979; Eddy, 1990; Fischer, Fetters, Munro & Goldman, 1997). Once this is accepted, then the broader issues of what makes a series of errors become an incident can be studied and analyzed, with the hope that the process can be improved to either mitigate that type of error or prevent it in the future. This has been the tactic that other industries have taken to analyze processes in order to reduce error, most notably the airline and nuclear power industries (Laffel & Blumenthal, 1989).

Another difficulty is defining specifically what it is that needs to be reported. There are many ways in which words can be parsed to define what the object of interest is. An event is considered adverse if it is an injury/insult that resulted from medical care provided in a hospital or healthcare setting, as opposed to injuries/insults resulting from the patient's condition or disease (Brennan, Localio & Laird, 1989). The Veterans Health Administration (VHA) defines adverse events as follows: "1) untoward incidents; 2) iatrogenic injuries; 3) unexpected occurrences; and 4) therapeutic misadventures resulting in negative consequences" (Veterans Health Administration [VHA], 1999, p.1). The VHA goes on to state that there are two major categories of adverse events, namely, sentinel events and unplanned clinical occurrences (VHA,

1999). A sentinel event constitutes a serious outcome, such as the loss of life, limb or a permanent loss of function. An unplanned clinical occurrence is less than a sentinel event, resulting in hospitalization as a result of an event or an increase in hospital stay or an error that has the potential to result in an adverse event (VHA, 1999). An avoidable error is one that results because of a mistake in thought or performance (Leape et al., 1991). The Army Medical Command (MEDCOM) issued a sentinel event policy which defines adverse events as "untoward incidents, therapeutic misadventures, iatrogenic injuries or other occurrences or conditions in the provision of care or services causing, or threatening to cause, unexpected harm to a patient" (U.S. Army Medical Command [USA MEDCOM], 2000). The objective is to determine if there is a method to identify and correct unintended action, before it becomes an event or an incident that may have a negative impact on patient care outcome. There is a need for a better system for recognizing and tracking adverse events as well as assessing their causes. Additionally, there should be a determination on whether an adverse event was preventable, and, if so, how preventive measures might be accomplished (Fischer et al., 1997).

The reporting form, itself, can be confusing for staff such that it may lead to a single error being reported more than once. In one hospital in Illinois what appeared to be a 56% decrease in the number of medication errors turned out to be due to the fact that fewer errors were actually reported (McNeilly, 1987). This illustrates a concern regarding the procedures for reporting adverse or sentinel events. The staff may not be aware of what should be reported or the mechanism of reporting an event. There may be lack of consistency in what gets reported. What is reportable and what is not may not be clearly defined for hospital staff. An anecdotal example will serve to illustrate this point. A purported equipment failure occurred at Winn Army Community Hospital (WACH) in the spring of 2000. According to the RN who identified the problem, there were several old examining tables whose electrical systems were shorting out, with the result that one patient and two staff members were "shocked" over a period of time. The very first incident of a person receiving a shock from the examining table should have generated a report to risk management and immediate resolution of the problem. The potential

for serious injury is not in doubt. The established process called for the RN to inform the Non Commissioned Officer in Charge (NCOIC) of the clinic. Unfortunately, the incidents were not reported with the result that additional people were shocked and the equipment was not identified as requiring immediate repair or replacement. Although it is arguable that the first incident was not preventable (depending on forseeability given the age and the status of the equipment), certainly the second and third incidents were preventable, had the process for reporting taken place, per established procedure. The anecdotal report of the examination tables shocking a patient and two staff members is an example of a latent failure. A latent failure provides the condition in which an unsafe act can occur (Vincent, Taylor-Adams, & Stanhope, 1998). In this case, there were several failures, to include inadequate maintenance of equipment, inadequate knowledge and inadequate system of communication.

The Institute of Medicine (IOM) published a report in November 1999 that brought swift and global attention to the problem of iatrogenic illness/injury to patients in the nation's hospitals. As an estimate, anywhere from 48,000 to 98,000 patients are killed annually from untoward medical mistakes occurring in American hospitals (Eisenberg, 1999; Resources for Reducing Medication Errors and Improving Quality in Hospital, 1999). One of the criticisms of the IOM report is that a clear cause and effect between adverse events and deaths was implied, but no direct correlation was demonstrated. A counter argument is that severely ill patients or those with complicated conditions were excluded from the study. In fact, because the IOM report was a retrospective study, it is likely that adverse events were missed because they were not recorded in the medical record. This does not begin to address the morbidity from adverse events which do not result in death, but which affect the well being of patients. Another concern for under estimating the number of adverse events is the fact that only those events occurring in patients admitted to hospital were studied, not those events which occurred in an out patient setting (Enright, Smith, Abel, Ramirez & Alsaggabi, 2000; State Health Watch, 2000). Moreover, little is actually known about the risks associated with outpatient care.

Although outpatient care is not immune from suffering adverse events, arguably, it is more

difficult to observe than an in-patient area. Proof of this allegation is the utter lack of studies in the literature quantifying the number of reported adverse events for out patients. In a rare study done at an academic medical center, in an out patient primary care setting, researchers documented a prevalence rate of 3.7 adverse incidents per 100,000 clinic visits over a 5 ½ year period (Fischer et al., 1997). Doubtless, this is not indicative of the actual total number of true adverse events, only those which were reported. Therefore, it is questionable whether this should be used as a benchmark for other academic medical centers. One could reasonably ask about what rate of errors would constitute an "acceptable" or benchmark error rate. Traditionally, healthcare professionals have not quantified meaningful rates for errors, in that it is the ideal to strive for as few errors as possible. The patient or the physician is probably not reassured by the fact that an error is within any so-called benchmark occurrence rate (Enright et al., 2000).

In Army medical treatment facilities, risk managers are tasked with keeping statistics on reportable adverse events. Fear of retribution, blame, loss of esteem, and possible reporting of healthcare practitioners to the National Practitioner Data Bank (NPDB) makes under reporting of incidents a real concern (Bagian, Gosbee & Lee, 2001). Medical professionals fear that information about errors will be used in court to litigate malpractice cases (Applegate, 1994). A study by the Department of Veterans' Affairs outlined some of the reasons there was wide variation among their facilities in reporting events, including fear of how the information will be used; too much paperwork; taking time away from important work and feeling that reporting of events does not accomplish anything (Adelson et al., 1998).

The proclamation from the IOM was merely the culmination of studies that had long ago recognized the problems with iatrogenic injuries, especially in the specialty of anesthesia (Andrews et al., 1997; Bates et al., 1998; Cooper, Newbower, Long & McPeek, 1978; Leape, 1994). The specialty of anesthesiology has made good use of the study of closed malpractice cases. Beginning in 1985, the Committee on Professional Liability of the American Society of Anesthesiologists (ASA) began a study of adverse outcomes, detailed information of which was present in claims files of a nationally group of insurance carriers. The group is called the ASA

Closed Claims Study. In this way, the professional society was able to use the cases to further their knowledge of those situations that would predispose a practitioner to commit an error. Through an objective analysis of data, they were able to use it to assist them in improving practice, for the benefit of their patients. By studying adverse events, it is possible to analyze what errors were repeatedly occurring in the process. In reviewing 1,541 closed claims, collected since 1985, they discovered that the single largest class of injury with regard to anesthesia involved the respiratory system (522 claims or 34%) (Caplan, Posner, Ward & Cheney, 1990). Three mechanisms of injury were responsible for 73% of the respiratory adverse events. They were inadequate ventilation (38%), esophageal intubation (18%) and difficult tracheal intubation (17%) (Caplan et al.). Methods used to monitor sufficiency of respiration included pulse oximetry, capnometry or a combination of both. (Caplan et al). In fact, in the last decade, the number of anesthesia related deaths has dropped from 2 per 10,000 to the current rate of 1 per 200,000 (Spath, 2000). To directly compare the two rates, this is equivalent to the anesthesia related deaths dropping from 40 per 200,000 to 1 per 200,000, which represents a highly significant forty-fold decrease.

The utility of using malpractice claims data to target individual practitioners, either by sanctioning them or referring them to additional training, has not necessarily proven effective (Adelson, 1997; Rolph, Kravitz, & McGuigan, 1991). In an analysis of malpractice claim records of New Jersey physicians with specialties of obstetrics/gynecology, general surgery, anesthesiology or radiology, spanning a time from 1977 through 1989, there was little evidence supporting the validity of targeting individual physicians as a negligence reduction strategy (Rolph et al.). The reason for this lies in the fact that it is not merely a few "bad" practitioners who are responsible for the majority of the medical errors. Rather, errors are distributed more diffusely. Thus, it makes sense to study processes rather than concentrating efforts on disciplining individuals, except where the error is egregious (Laffel & Blumenthal, 1989). It has been shown that malpractice data can be effectively used to identify problem-prone clinical processes (Kravitz, Rolph & McGuigan, 1991). In the same study of New Jersey physicians

cited previously, problems in patient management resulted in the most frequent errors in all four specialties. The utility of knowing which processes are most problem-prone is to use that information to suggest interventions that may reduce the number of adverse events (Kravitz et al.).

An analysis of adverse events might be an outcome measure of the quality of care (Brennan et al. 1989). Feldman & Roblin have made a distinction between adverse events and medical accidents, in that they consider preventable medical incidents to be medical accidents. They are usually associated with an unsafe act that precipitated the event and a fault in the process or system. A systematic analysis of events in the evolution of a medical accident can lead both to discovery of system faults and to recommendations for possible corrective system changes (Feldman & Roblin, 1997). The overarching goal is reduction in the rates of adverse outcomes. "Understanding of causal factors in the evolution of medical accidents can be usefully applied toward improvement in the quality of hospital appraisal of iatrogenic injuries and, through that application, toward reduction in the rates of adverse outcomes" (Feldman & Roblin, 1997, p.577). The point is that if health care organizations can begin to understand the connection between their outcomes and their processes, it can only serve to improve health care (Weinberger, 1996).

As a direct result of the IOM study, in February 2000, the President unveiled a series of initiatives designed to improve patient safety and reduce the number of adverse events caused by preventable medical errors. Key elements include: mandatory reporting requirements of preventable medical errors causing death or serious injury; a new Center for Quality Improvement and Patient Safety; new standards to be developed by the Federal Drug Administration (FDA) to reduce medical errors; and the modernization of patient safety systems at the Department of Defense and the Department of Veterans' Affairs (Association for Health Services Research, 2000). The Department of Defense (DoD) has responded to the Presidential directive by forming a Defense Patient-Safety Working Group (DPSWG) that is in the process of publishing a DoD Instruction (DoDI). The idea behind the initiative, which is in concordance

with the IOM and the American Medical Association (AMA), is to prevent errors, rather than punishing them (Noyes, 2000b). The instruction will be used to guide creation of patient-safety programs in all military treatment facilities (MTFs). The goal is to cut medical errors by 50% over a five-year period (Noyes, 2000a). Because of traditional past behaviors of concentrating on individual adverse events, and seeking to blame specific practitioners, it is understandable that there was underreporting of adverse events. Contrariwise, the DPSWG will be seeking to change the perception of blame, concentrating instead on voluntary reporting and on systems, rather than individuals. They also propose analysis of cases and sharing valuable lessons from said analyses. Aggregated data will be used to derive lessons, to eliminate the possibility of recognizing individual events. It is likely that reporting will be directly to the Armed Forces Institute of Pathology (AFIP), rather than through individual MTF command channels.

According to Dr. Martin Boyle, hospital lawyer for the Audie L. Murphy Veterans Hospital in San Antonio, TX, "A good risk manager is someone who goes to work in the morning and firmly believes that the hospital is going to kill someone that day, and tries to think of things they could do to prevent it" (M. Boyle, lecture given at the U.S.Army-Baylor University Graduate Program in Healthcare Administration, January 13, 2000). The operative point is to be proactive. JCAHO has recognized this, in that since 1999, there has been a mandate to reduce sentinel event risk by studying the frequently occurring sentinel events in health care organizations (Kobs, 1998).

Methods and Procedures

There were several questions I hoped to answer by conducting this project. Can education and encouragement to report increase the number of reported events? Was it possible to make an automated intervention to decrease the number of prescription errors? What would analysis of the risk management database reveal about trends and reports and how well did this correlate with known litigated cases?

The null hypothesis is stated as follows: interventions designed to increase reporting will have no effect on the number of reported errors. The alternate hypothesis states that there is a

relationship between interventions to increase reporting and the number of reported events and the relationship is a positive one. The premise is that if the interventions work, then the number of reports should increase. The independent variables are specific interventions designed to increase reporting of errors/incidents. The dependent variable of interest is the number of reported incidents.

Another null hypothesis is that there is no relationship between changing a process for filling prescriptions and the number of prescription errors. The alternative hypothesis states that changing a process for filling prescriptions will directly affect the number of prescription errors and the relationship will be in a negative direction. The premise is that if the process is successful, then the number of errors should decrease. The independent variable is the automated intervention to decrease the number of medication errors. The dependent variable of interest is the number of medication errors.

Interventions were designed to increase the number of voluntary reports made to the health Risk Manager. A multifaceted approach, using different error reduction messages, given in different venues and locations would appear to increase the utility of the design. Thus, multiple interventional efforts were made to increase the awareness of the importance of reporting incidents, both "near misses" and actual incidents with negative outcomes for patients. The first intervention was put out for all staff at WACH. They were informed about a miniseries entitled, "Why Doctors Make Mistakes" (Stewart, 2000). This was aired on The Learning Channel® on November 20th and 21st, 2000. This served as a foundation for adopting a non-punitive approach, as the main message was that healthcare providers should not be treated as criminals. Rather, active communication about process improvement should be encouraged. For those staff members who were unable to see the program, the hospital safety/security department planned to tape the program for ease of viewing at a later date.

Continuing the interventional effort, I gave a one-hour lecture for continuing medical education credit (CME) in two locations on 11 January 2001. The lecture, entitled "Medical Errors", was primarily targeted toward the healthcare provider population (see Appendix A).

The intent was to inform the audience of the background leading up to the current focus on medical errors. More importantly, it was designed to encourage the reporting of events, reassuring providers that the cultural climate would be non-punitive. Included in the lecture was a personal anecdote about a patient who had been treated for esophageal candidiasis who was later found to be positive for the human immunodeficiency virus (HIV). This anecdote was purposely included in order to share an experience that would demonstrate a need for disclosure. In addition to the lecture, a 10-minute video detailing a few anecdotal cases was presented (Bridge Medical, Inc., 1998). The content of the video was directly culled from the miniseries previously sited (Stewart, 2000).

On 18 January 2001, I reiterated the need to report medical errors to the Committee on Risk Management during its monthly meeting. The Deputy Commander for Clinical Services (DCCS) chairs the meeting and the Risk Manager conducts the meeting. The medical directors of the emergency room (ER), pathology, family practice and psychiatry were present. Additionally, the Assistant Director for Nursing Services represented the department of nursing. Discussion ensued about the fact that some, if not all, departmental errors are handled internally. As an example, the chief of pathology informed the group that they dealt with errors internally and never felt the need to report specific errors to the Risk Manager. The DCCS stated that there would be occasions when internal errors within pathology may affect the hospital in general and that these would be the types of reportable errors that should be reported.

On 22 January 2001, I presented a 15-minute talk in the newcomer's briefing. Individuals recently hired as well as newly arrived military personnel are required to attend. I spoke to them about the history and the need to analyze "near misses" in order to look at processes. I made a point of stressing the fact that methods would not be punitive. I demonstrated the form that WACH uses for reporting incidents. I told them that they did not have to go through their supervisor if they felt uncomfortable doing so, rather, it was acceptable to put the form under the door of the Risk Manager in an anonymous fashion. I gave them the number for the Risk Manager as well as my own phone number. In order to encourage reporting, I related one of my

own medical errors, as was done previously, as part of the intervention, to demonstrate that we all make mistakes. This incident occurred in 1976, when I was a student nurse at the Gloucestershire Royal Hospital in Gloucester, England. I had drawn up a pre-operative injection of morphine for a patient. She was an unusually thin patient and the anesthesiologist had ordered half the usual preoperative dose for her. Instead of reading the dosage, I gave her the usual adult dose, which was twice the indicated amount. I only realized my mistake after I had administered the whole syringe. I immediately informed the charge nurse, who informed the anesthesiologist, who was then able to adjust what she did for induction. If I had kept quiet, it is likely that the patient would have had a respiratory arrest, and the anesthesiologist would not have understood why. None of us is infallible. The shame doesn't accrue in making the mistake, only in failing to do something about it, once it is known.

The database that is used at WACH is based on a database using dBase III, Version 3.0 for quality improvement/risk management that was developed by the risk management department at Martin Army Community Hospital (MACH) in Fort Benning, Georgia (Rooks, 1993). Error codes, specifically defined by MACH for the database, are not universally used throughout the Department of the Army (see Appendix B). The risk management database encompasses data from four full fiscal years, 1997 through 2000, representing 1,443 records. The database for October 2000 through February 2001 (partial fiscal year 2001) added 87 additional records, bringing the total number of records to 1,530. (A fiscal year (FY) is defined as starting on 1 October of a given calendar year and ending on 30 September of the following calendar year). In terms of what is reported to the Risk Manager, the system is both passive and sporadic. To actively pursue information about possible adverse events, the Risk Manager attends the morning nursing report. In this venue, she may hear of situations that bespeak of possible errors. She also maintains close ties with the patient representative who is often the first person a patient turns to when they feel something is wrong. The database of reported events was statistically described, using histograms and line graphs for illustration. Analysis included the gross number of all reportable events, as well as rates of errors for the outpatient population at WACH. Gross

numbers of incident reports were trended by month and fiscal year. Additionally, the incident reports were trended by location and fiscal year. If an error or incident was reported more than twenty times in the database, over the four-year period, it was considered "common". In this context, common types of problems were represented in a histogram for trend. When errors were consolidated into treatment related, diagnosis related or medication related categories, they were trended by clinic or department. The rate for reported errors in the outpatient arena at WACH was calculated as the number of adverse events in the outpatient department per number of clinic visits. These rates were used as internal benchmarks for WACH. Rates were compared for trending over complete fiscal years. The mean rate was determined for each fiscal year containing complete data, with determination of upper and lower control limits by adding and subtracting twice the standard deviation to and from the mean, respectively. Statistical tests to compare means of reported events by month and fiscal year were computed using statistical testing procedures within software from Exel™.

For ease of manipulation, and after consultation with the chief of pharmacy, information about medication edits was downloaded from the Composite Health Care System (CHCS) into an excel database. This took advantage of data that were already being collected by the pharmacy, which involved the number of edits that have to be made for prescriptions. Pharmacists make edits when they see that a prescription is faulty in the way it is written. This is distinguished from making an intervention where a pharmacist needs to converse with the prescribing physician about his intent. An edit is necessary when the correct number of pills is not specified or the dosage is not clearly spelled out, as examples. The edits were of many varieties, including changing the total number of pills required, clarifying the instructions for the patient and properly delineating the route of administration. Edits cross the spectrum of errors related to prescriptions such as: wrong medication, wrong route, wrong dose, omitted dose, incorrect time and concern about appropriateness of medication (Carey & Teeters, 1995). The rate for medication edits was calculated as the number of edits per number of prescriptions written. Default prescriptions were created for those drugs for which there were 15 or more edits

(total 24 items). This method allowed the ordering physician to simply choose the script without having to manually type it into CHCS. This concept was introduced at the medical executive committee meeting on 15 November 2000. Although only four physician chiefs were present, representing surgery, primary care, pathology and the emergency room, there was hope that they would foster the idea of using default prescriptions through their interaction and influence with other medical staff members. It was also presented at the medical risk management peer review/ meeting on 16 November 2000. Statistical tests to compare paired samples for means of the number of edits (before and after the introduction of default prescriptions) were computed using statistical testing procedures within software from Exel™. In addition, confidence intervals for the difference in paired samples were calculated using methods described in a statistical text by Motulsky (Motulsky, 1995). Types of medication errors within the database were quantified by percentage of the total database.

Obtaining valid and reliable data from reported adverse or potentially adverse events is challenging. Because not all events are necessarily reported to the Risk Manager, the data does not completely reflect the universe of actual adverse or potentially adverse occurrences (van Leeuwen, 1994). Therefore, the actual rate of errors can never be known with any accuracy, because the total number of occurrences which makes up the denominator will likely never be known (Cullen et al., 1995).

An analysis of closed and pending lawsuits filed against WACH from four fiscal years (FY 98-00) was used to determine the common risk-prone types of errors that should be monitored for performance improvement. "A comprehensive error reduction initiative should include both process and outcome measures" (Ferraco & Spath, 2000, p. 26). Filed malpractice claims are not necessarily valid, simply because a patient has filed a claim. There are frivolous lawsuits. Lawsuits are filed even when no clinical error has occurred. Peer review has borne out the fact that the outcome does not determine whether standard of care was met in taking care of a patient. Bad outcomes can and do occur in spite of clinicians performing perfectly and meeting or exceeding standard of care (Holder, 1972). Likewise, good outcomes can occur even if standard

of care is not met, attesting to the resilience of patients. On occasion, they get better in spite of medical care! Department of Defense (DD) form 2526, promulgated in October 1992, is used when a case comes up for peer review. The codes used in DD form 2526 specify act or omission codes with regard to malpractice. It uses a different system of coding than the codes for errors in the risk management database (see Appendix C). This brings up the question of validity, as to whether the same thing is being measured between an incident and a subsequent malpractice case, should it progress to that.

Results

The data were analyzed for trend in terms of total number of reports. The number of reports by FY were as follows: 407 (FY 97), 453 (FY 98), 315 (FY 99) and 268 (FY 00). A line graph demonstrating the trend is depicted in Figure 1. It is clear that the number of reports has diminished and flattened out. Peaks of reporting were apparent in March and April of '97 and '98 and only one report, each, for the months of July and October in '97.

The histogram in Figure 2 represents 959 records and illustrates the common types of problems that were reported. The remainder of the records in the database (484) represent problems in which the count was fewer than twenty.

When looking at an ambulatory venue versus an in-patient setting, 22 of the reviewed cases were in an outpatient setting (19%). From a strictly in-patient setting, there were 34 cases (30%). The emergency room accounted for 30 cases, or 26% of the reviewed cases. Combined, the emergency room and the in-patient setting account for half of the reviewed cases (56%).

Three specific types of errors, diagnosis-related, treatment-related and medication errors, were reviewed across major departments from both in-patient and outpatient areas. Figure 3 shows that most medication errors were reported from the intensive care unit and the in-patient wards, while none were reported from the family practice out patient clinic.

When incident reports from Winn Army Community Hospital, exclusive of reports received at the outlying soldier family health clinics and the satellite clinic at Hunter Army Airfield in Savannah, were analyzed by location and fiscal year, the same pattern was borne out

over all years, as seen in Figure 4. The category of "other" included areas such as hallways, front entrance, radiology, and administrative areas, etc. Many of the falls fit into this category. It is apparent that reporting was higher in the inpatient area for fiscal years 97 and 98, when compared to fiscal years 99 and 00. In the aggregate, when comparing the total number of reports across fiscal years, the differences in means were not statistically significant. However, in separating out the inpatient reports, which can be seen to be the consistently high peaks on the graphs, the mean number of in patient reports was significantly higher in FY 98 (19.75) compared to both FY 99 (12.17) $p = 0.047$ and FY 00 (10.92) $p = 0.36$. Additionally, inpatient reports were significantly higher in FY 97 (17.92) compared to FY 00 (10.92) $p = 0.035$. Inpatient areas consistently reported the highest number, followed by the emergency room. Consistently, outpatient and pharmacy had the lowest number of reports.

Reports in the first five months of the new fiscal year (FY 01) were analyzed to determine if there was a statistically significant increase in the mean number of reports, in order to test the hypothesis that interventional efforts would positively increase reporting. When the number of reports in each month was compared with the previous fiscal year (FY 00), there were no statistically significant differences in the mean number of reports, with the exception of February as seen in Table 1. In fact, the opposite of the anticipated outcome occurred, in that the mean number of reports in February of FY 01 significantly decreased in comparison to February of FY 00 (2.4 vs. 6.2; $p = 0.047$).

A benchmark was developed with regard to error rates, based on the reported out patient errors per number of outpatient visits. Figure 5 shows that the mean rate for FY 00 was 3.5 incidents per 10,000 outpatient visits. When compared to other fiscal years for which there is complete data (FY 99 and FY 98), there are no statistically significant differences among the rates, even though the mean gradually dropped over the years; the mean rate was 4.3 and 4.0 for FY 98 and FY 99, respectively. Figures 5, 6 and 7 depict control charts for fiscal years 98 through 00, demonstrating that reported rates are "in control", staying within upper and lower control limits, defined as the mean plus and minus two standard deviations, respectively.

There were 2,188 edits out of a total of 78,033 new prescriptions filled for the months of August through October 2000. This is a rate of 2.8 %. Figure 8 shows a histogram depicting the number of medical edits for twenty-four specified drugs. A t-test was done for paired two sample for means, in order to test the hypothesis that an automated effort would decrease the number of pharmacy edits. The mean number of edits for the twenty-four drugs listed from August through October 2000 was 24.54. The mean number of edits for the same group of drugs from December 2000 through February 2001 was 10.13. Both the one-sided as well as the two-sided p values were highly significant at 1.52×10^{-6} and 3.04×10^{-6}, respectively, as seen in Table 2. The 95% confidence interval (CI) was 9.538 to 19.302, excluding one, and corroborating the significant magnitude of the difference.

The first nine types of error account for eighty-four percent of all the medication errors reported in the database as illustrated in Table 3. Thirty-six percent of the errors involved failure to administer medication as ordered. Interestingly, although medication errors constitute 19.3 % (279 reports) of the database, only two cases involving medication errors were reviewed for standard. Medication errors, although numerous, clearly were not of a severity level to substantiate significant patient harm. Of the two medication error incidents that were reviewed for standard of care at WACH, one involved failure to administer medication as ordered and the other was administration of the wrong dosage. The result of the standard review was that the wrong dosage clearly did not meet the standard of care, it resulted in the need for monitoring but no significant patient harm. The other situation met the standard of care and involved a misunderstanding on the acceptable parameters of a magnesium sulfate infusion in a patient in preterm labor. The paramedic questioned the physician about what the correct infusion rate should be. When the resident responded that it should be 2 grams per hour, the paramedic rejoined that it was running at 5 grams per hour. The resident stated that that amount was acceptable.

Of all reported incidents in the database, the review of the pending and litigated lawsuits, revealed that only nine have been litigated to date (0.62 %). Other cases may still be brought or

are pending review of standard of care. There were 114 records that were reviewed for standard of care. Fifty-one of the 114 did not meet standard of care (44.7%); whereas fifty-nine did meet the standard of care (51.7%). Four cases were deemed to be of indeterminate standard. Fifteen (29.4)% of the cases which did not meet standard of care involved diagnosis related issues; i.e. failure to diagnose, delay in diagnosis and wrong diagnosis. Likewise, fifteen (29.4%) involved treatment related issues. Nine (17.6%) were considered *res ipsa loquitur* ("the thing speaks for itself") in that foreign bodies were left after operative procedures in eight of the cases and one case involved an operation on the wrong body part (Holder, 1972). Altogether, the emergency room (ER), operating room (OR) and labor & delivery accounted for 61.4% of the reviewed cases. The ER accounted for 30 of the 114 reviewed cases (26.3%), of which, 15 did not meet the standard (50%); 13 met the standard (43%) and two were indeterminate (7%). The OR accounted for 21 of the reviewed cases (18.4%), of which, 10 did not meet the standard (48%); 10 met the standard (48%) and one was indeterminate (4.7%). The labor & delivery service accounted for 19 of the reviewed cases (16.7%), of which, 8 did not meet the standard (42%); and 11 met the standard (58%).

An analysis of pending lawsuits revealed that most cases involved either a delay in diagnosis or a misdiagnosis and incorrect treatment. Corroborating this, of the nine cases already litigated, four involved diagnostic related issues, four involved treatment related issues and two were retained foreign bodies. None of the medication error incidents were litigated. Three cases, illustrating common issues of diagnosis and treatment errors, as well as a lawsuit without merit are presented in order to illustrate the results of the lawsuit review.

YG was a 46-year-old male who was initially seen in the emergency room on 4 May 1999, complaining of an earache that he had had for three days. He was diagnosed with an otitis media (infection of the middle ear) in his left ear. He was treated with antibiotics, pain medication and a decongestant. He was seen in follow up in the family practice clinic three days later on 7 May 1999, and stated that he did not feel better. The recommendation was to continue the treatment regimen. He had a third visit on 21 May 1999, in family practice, and he continued to complain

of pressure in his left ear. His tympanic membranes were noted to be normal. On his fourth visit, on 5 June, he requested a referral to the otolaryngologist (ENT) for his ear infection. It was noted that he had decreased hearing in his left ear and he was diagnosed with a serous otitis. By his fifth visit, he was still complaining of an ear infection and the diagnosis remained serous otitis. He was given another antibiotic. He and his wife, who was active duty, relocated to Korea. He was seen at the 121st Hospital in Seoul on the 23rd of September 1999 by an audiologist. This resulted in the first objectively documented evidence of a sensorineural hearing loss of 1,500-4,000 Hz and a reflex delay in his left ear. After a referral to ENT and a magnetic resonance imaging study (MRI) of his brain, he was diagnosed with a mass lesion that was consistent with an acoustic schwannoma. Ultimately, he was air evacuated to Tripler Army Medical Center in Honolulu, Hawaii, where he underwent an operation on 9 February 2000. The final pathology of the lesion revealed that it was a vestibular schwannoma. The end result is that he was left with complete hearing loss on the left side. Ironically, the outcome would probably have been the same, had he been diagnosed somewhat earlier, because the lesion had probably been present for two to three years prior to becoming symptomatic. The case is currently under review for standard of care. However, the point remains that this patient had multiple visits in which his condition was not improving, and there may have been an opportunity to assign a case manager or discuss the case with a specialist. He is suing the Army for $500,000.

A case that illustrates incorrect treatment involves an 18-year-old female, TG, who was involved in a motor vehicle accident (MVA) on 17 February 1996. She was seen in the emergency room at WACH, having been found in a supine position by the ambulance crew. Among other injuries, she had laceration injuries of her left forearm and wrist. The attending physician felt that she had soft tissue injuries in her left forearm, and had the wound irrigated with one liter of normal saline. He had a medic suture the wound closed without a thorough exploration. He stated in a later deposition that he was of the opinion that the surgeon he consulted would re-open the wound and examine it under anesthesia for tendon injuries. In fact, the patient's left arm and hand were grossly infected with frank pus that was readily apparent

when the wound was re-opened two days after the injury. Glass particles, grunge and "road rash" were present in the wound and two tendons were lacerated (the extensor indices propius and the extensor digitorum longus). The repair was complicated by the delay in treatment, with the outcome being permanent contracture of the hand. The standard of care was not met in this case, as it is not acceptable practice to close a wound when a tendon injury is suspected. The patient is suing for $1,000,000.

Some lawsuits filed had no merit, from the perspective that, in spite of having a bad outcome, there was no breach in standard of care. This corroborates the fact that outcome does not determine whether standard of care was met. One such case follows. MJ was a 27-year-old female who was seen on 29 October 1996 for removal of a mole from her right breast. She had 10 subsequent visits related to the sequelae from the initial procedure. She alleged that she was the victim of malpractice because she sustained an infection and had significant scarring. In fact, prior to the procedure, the risks were explained to her, including the complications that could result, including infection and scarring. This case was not only reviewed by the internal peer review committee at WACH, but also by the Consultation Case Review Branch (CCRB) at Walter Reed Army Medical Center (WRAMC) in Washington, D.C. Both organizations deemed that standard of care had been met. The plaintiff had been offered the opportunity to produce expert medical witness/testimony as to the lack of standard of care. Failing to be able to do so, the claim was denied and the case was administratively closed.

Discussion

An error reduction initiative is not going to be an easy or straightforward program to initiate at WACH, much less at the MEDCOM level for uniform exportation throughout all MTFs. The reasons are both intuitive and obvious. Foremost is the human factor. Like all human beings, physicians make mistakes and have "near misses". Culturally, health care providers, and, physicians in particular, have been taught to succeed. They are held up to a very high, occasionally impossibly high, standard. This is not to imply that medical errors are covered up. Rather, when mistakes and "near misses" occur, it is difficult to discuss them openly and

without recrimination. This is understandable in view of the extremely litigious society that American has become. There is a fear that peer review discussions may be disclosed and that practitioners may find their names submitted to the NPDB (Bagian et al., 2001). The reality is that very often, it is not just one practitioner who is at "fault", but a system that allows errors to occur (Cohen & Smetzer, 1999).

The original concept for the graduate management project was to determine those areas that were most risky and to attempt to find a systematic way of analyzing and finding solutions for process errors. It became obvious that this type of task was onerous. The DPSWG, itself, is struggling to develop a course to teach methods of looking at risky processes, dissecting them and developing viable solutions to change.

One of the goals put forward by DoD is to reduce the amount of errors by 50% in the next five years. However, this type of goal was referred to as "stretch" goal by CDR John McQuestion in his presentation for the Medical Executive Skills Training course at Fort Gordon Georgia (personal communication, CDR John McQuestion, 6 February 2001). A "stretch" goal is simply a guess, because there is no information about the number of medical errors that constitute the baseline, such that MEDCOM would know when that initial number had been successfully reduced by 50%. There is an old Sioux proverb that says if you don't know where you're going, any path will take you there. The operative point is that we should know where we're starting out to know how far we've come, or where we're going. Thus, I decided to take a more prosaic as well as practical approach in order to determine the baseline for medical errors at WACH by analyzing and describing the risk management database that has been used for the past four years.

What is immediately apparent in the WACH risk management database is that 1,443 incidents represent an apparently unrealistically low amount of reports for a four-year period. This clearly reflects problems with reporting in that the database does not reflect the actual number of events, but only those which are reported. The Presidential directive and its planned execution by the Department of Defense (DoD) are predicated on reporting medical errors. The

Presidential directive promotes mandatory reporting. Databases that rely on adverse reporting are known to be inaccurate, even when state and federal regulations mandate reporting (Spath, 2000). DoD is promulgating voluntary reporting. It is known that voluntary reporting only represents a small fraction of the true universe of "near misses" and incidents that occur. It is known that providers are reluctant to report for reasons previously cited, including fear of reprisal, loss of self-esteem, fear of litigation and reporting to national data practitioner banks, with all of the "fallout" that that entails (Bagian et al., 2001; Dutton, 2000; Tribble, Lamnin & Garich, 1985). Of interest, is that in the civilian arena, the one case that is held up as a model for voluntary reporting and disclosure occurred in 1995. It involved an anesthesiologist injecting the wrong drug into a young boy during surgery, ultimately costing the child his life. The fact that it occurred six years ago and appears to be the only publicly lauded model attests to the fact that reporting and absolute disclosure to family members is fairly rare (Bridge Medical, Inc. (1998). It must be said that the VHA encourages disclosure to family members and has found that the number of medical malpractice lawsuits has not increased substantially. By the time events are usually reported, it is long after the fact and the effort to understand the process may be hampered by the lack of timeliness. The issue is whether one can legitimately gather any information on "near misses". Providers likely do not report "near misses", perceiving that where there is "no harm, no foul". While on the surface of the argument that an error that doesn't result in any harm to a patient makes intuitive sense, it robs the organization of the ability to analyze the potential for injury. Ultimately, if the process is faulty, and there is no warning because "near misses" are unreported, a patient may be harmed when a similar situation arises. Reporting of "near misses" requires unusual dedication and commitment over and above what a reasonable provider is currently expected to do. With all of the administrative burdens placed on military providers, including charting, attending to data within CHCS, ensuring accuracy in coding and diagnoses, among other responsibilities, it is unrealistic and fanciful thinking to expect providers to report on "near misses". The amount of information presented to a physician is daunting and it has been hypothesized that it is more than one can reasonably

process without error (McDonald, 1976). Reporting is also personality dependent, in that providers who are compulsive and have demonstrated a tendency to report are more likely to report, regardless if the reporting is voluntary or mandated. If the DoD relies on reporting and bases decision-making on inadequate, unreliable and invalid data, then the results must be questioned.

There are faulty assumptions that have been made in designating quality improvement initiatives to be based on data from risk management databases. There is no evidence to date, linking patient outcomes with reported events. Dr. Charles Billings commented that simply counting voluntarily submitted incident reports is a waste of time (Spath, 2000). Rather than counting the numbers of adverse events, it is more important to look at common causes of events (Spath, 2000). Litigated claims are not usually represented in the risk management database. It may come as a surprise that there is little, if any correlation, between the claims information and reported incidents. As mentioned previously, of all the cases represented in the database, only nine were litigated (0.62%). On peer review, none of these cases met the standard of care. There may be other explanations for the lack of correlation between reported incidents and litigated cases. Analysis of the database indicates that outcomes of most reported events are not serious. Moreover, some malpractice cases are without merit. Of all medical malpractice lawsuits filed in the United States, less than 10% of them have evidence of a clear adverse event constituting malpractice (Spencer, 2000). Within WACH, the majority of meretricious lawsuits that were successfully litigated, from the plaintiffs' perspective, concerned delay in diagnosis, treatment errors and retention of foreign bodies. Most errors, in fact, do not result in patient harm or injury, and are not reported. In a study that used a database detailing 9,000 medication errors from 25 different hospitals, over 50% were caught before reaching the patient. Of those that were not caught, 91 percent caused no harm to the patient (Resources for reducing medication errors and improving quality in hospital, 2000). There is evidence to suggest that egregious errors will be reported and analyzed. If not, they will likely be uncovered by lawsuits subsequently filed. However, not even egregious errors are necessarily reported.

Evidence and experience does not bolster the assumption that serious incidents will necessarily generate reports. In a study by Cullen et al., twenty-six of the adverse drug events reported were classified as serious or life-threatening, and only two of them had been reported as incidents (Cullen, et al.1995). In one study looking at patients admitted over a six month period to a medical care intensive unit, surgical intensive care unit and general medical care unit at a specific hospital, 54 adverse drug events occurred, only three of which were documented by incident report (Cullen, et al.). Allen and Barker found that only .07% of medication errors documented by direct observation was represented by incident reports. Of a total of 51,200 extrapolated incidents, only 36 were reported (Allan & Barker, 1990). During the course of the project, I personally became aware of an incident involving a patient overdose. The prescription had been written by a civilian physician for a military beneficiary and filled by the pharmacy at Tuttle Army Health Clinic in Savannah. The prescription was transcribed incorrectly with the result that the patient took twice the normal amount. This resulted in an emergent hospitalization for acute tubular necrosis, from which the patient later fully recovered. If I had not been present at the civilian hospital during a rotation when the patient was admitted, an incident report would never have been filed in the risk management database at WACH. It may never have come to light until and unless a lawsuit was initiated. Neither was there evidence for communication between the risk management department at the civilian hospital and WACH. To date, no one from the civilian hospital has contacted WACH's Risk Manager to discuss this "shared" case.

A potentially false assumption with regard to reporting is that a hospital with more reported errors is less safe than a hospital with fewer reported errors. Realistically, it may be precisely the opposite conclusion that should be reached. Unfortunately, the issues with reporting are more complex than the mere numbers may suggest. A hospital that has an active program to ferret out medical errors and report them may be doing a better job with regard to patient safety than a hospital with very few reported errors. A high error rate may suggest active error reporting or it could suggest unsafe medication practices. Conversely, a low error rate could be indicative of successful error prevention or inhibition of error reporting because of a punitive

organizational culture (Cohen, 1999). A couple of parallel arguments support the concern about drawing simple conclusions from numbers of reports. In my opinion, it has erroneously been concluded that Ft. Stewart has a significant problem, ranking third out of all Army posts, behind Ft. Hood and Ft. Bragg in total numbers of cases of spouse and child abuse. More appropriately, I would suggest that Ft. Stewart has an excellent program in social work services and has done an exemplary job of case finding and case management. It is not so much that Ft. Stewart has a great number of cases, but that other posts may not be as active in uncovering the cases that exist (personal communication, MAJ Edgar Habeck, Chief of social work service, WACH). Relying solely on reporting as a gauge of social well being, the Army could incorrectly conclude that spousal and child abuse was more rampant at Ft. Stewart than other posts. Another argument belying the utility of blind trust in reports is the fact that most physicians have little use, patience or understanding for reporting diseases and conditions that are deemed to be mandatory reports to the state. As a board-certified preventive medicine physician with thirteen years of specialty practice, I can attest to the fact that there has to be active surveillance in order to find "reportable" diseases. If we waited for military physicians to report disease, we wouldn't find much.

This project demonstrated that reporting did not significantly change in spite of providers being provided the rational and educational impetus to do so. Although some research has demonstrated that a physician reporting system can be efficacious in a teaching hospital, the fact that there were no significant differences in the mean number of reports following interventional efforts is not unexpected (O'Neil et al., 1993). There is much in the literature to support the fact that educational efforts to promote reporting do not make a difference in the amount of reporting (Berwick, 1996; Cullen et. al., 1995). It must also be mentioned that the period of time for making interventional efforts was short. It remains to be determined if a longer period of intervention with more educational activities would have made a difference. However, this is highly unlikely, given the point that education about the importance of reporting is not enough. I do not want to give the impression that those in the risk management field should be

discouraged; quite the contrary. All of this rhetoric serves to point out the fact that reporting should be encouraged, but it should not be the sole mainstay and bastion for an error reduction initiative.

By the same token, the benchmark that I developed for outpatient error rates cannot be considered a "true" benchmark and must be qualified. Although rates can be calculated from the data, they may have little meaning, because the true numerator (the total number of occurrences) can never accurately be known. Because the actual incidence of errors is unknown and is dependent on the vicissitudes of reporting, any resultant calculated rates are spurious (Cohen, 1999). Undoubtedly, this is one of the factors contributing to the paucity of information on error rates in the outpatient arena. The average rates for WACH at 3.5 per 10,000 visits are ten times the rate in an academic medical center, at 3.7 per 100,000 clinic visits (Fischer et al., 1997). This does not necessarily mean that the rate at WACH is alarmingly high. For similar reasons, previously discussed, WACH may be doing a better job of discovering and reporting errors than the medical center. The medical center may have emphasized in-patient reporting because it was easier to procure data than in the outpatient arena. Undoubtedly, there are a whole host of factors that play a role in the apparent disparity. If one looks at the reporting of medication errors, alone, it makes intuitive sense that errors occurring in an in-patient setting would be more readily apparent than those committed by a health care provider in an outpatient setting, excluding those discovered by the out patient pharmacy. This is clearly borne out by the pattern of reporting seen at WACH. The search for a legitimate benchmark must be predicated on the use of objective measurements of errors, rather than placing sole trust in the reliability of spontaneous reporting (Cohen, 1999). Additionally, to be useful for comparison with similar healthcare organizations, a benchmark should comprise clear and consistent terminology and definitions of what it is measuring. It is apparent that DoD has no standard definitions of reportable events in terms of coding. The risk management database that WACH uses had been briefed at the MEDCOM level, but not adopted as a DoD standard (personal communication, Mr. Michael Wolfe, 23 February 2001). Further, the classification system for coding has been

relegated to each MTF for internal determination, so there is potential for as many different classifications as there are MTFs. Since MTFs throughout the Army are using other, locally developed codes in their individual risk management databases, the problem is readily apparent that it is impossible to make legitimate comparisons among MTFs. Thus, the information cannot be used for legitimate benchmarking between like-sized healthcare facilities, due to the lack of consistent definitions and coding. Moreover, the codes used in the peer review process bear no relationship to the codes used in the aforementioned database tracking and trending system.

Interestingly, the highly significant results from using an automated intervention in reducing the number of pharmacy edits are compelling. This has a direct impact on improving care, in that default prescriptions clearly decreased the number of edits for faulty prescriptions. This project showed a distinct advantage in using an automated effort as opposed to relying on a voluntary one. In doing so, it demonstrated the worthiness of using an automated solution to change a process. The healthcare provider is relieved of the burden of typing in the prescription every time. More importantly, he knows that if he simply chooses the default prescription, its formula will be correct.

Choosing the right performance measure is important. "The ultimate purpose of patient safety performance measures is to reduce the number of avoidable patient injuries and deaths. To achieve this purpose, safety-related performance measures must be like the canary in the coal mine, providing a reliable early warning of safety-related problems" (Ferraco & Spath, 2000, p. 23). The challenge is to create an "error reduction initiative" which would fulfill the requirements of a proactive risk management approach. Given the statistically significant success of the automated effort in reducing pharmacy edits, it would appear that the more we can rely on automated solutions, the further progress can be made in error reduction.

Conclusions and Recommendations

All the evidence presented, both from literature review and the experience during the management project at WACH suggests that a multifaceted approach would be best to effect error reduction and enhance patient safety. DoD is embarking on a plan to require voluntary

reporting. Although I think that the plan should incorporate and encourage voluntary reporting, I think it would be misleading and erroneous to rely solely on information gleaned from reported incidents. The answer may lie in understanding that reporting, voluntary or mandatory, is only part of the equation, and, in fact, perhaps only a minor part. If reliance on reporting, alone, leads to bias, a reasonable question would be "How should we go about obtaining information on medical errors such that we can review faulty processes and make appropriate interventions to effect positive outcomes?" A better proposal would be to develop a systematic way of gathering data on processes prone to medical errors, not subject to the vagaries of reporting. As stated in the discussion, the actual performance improvement in the number of pharmacy edits gives credence to automated initiatives. If a more objective, computerized screening and detection program were developed, it would more accurately represent the universe of incidents. Further, those incidents that are likely to result in patient injury deserve the most concentrated effort rather than looking at all errors. As was seen, it appears that most reported errors are not associated with significant outcomes.

DoD has an existing computerized information system, CHCS, which is used to gather patient information. I would propose that specific ad hoc reports be developed using CHCS to extract data on potential problems, which can then be subsequently analyzed to determine if "near misses" are likely. This would be a more efficacious use of resources. It would also link outcome to event and would provide a better mechanism than the current reporting system for determining if there is a linkage between "near misses" and outcome events. Outcome information, until recently, was not systematically entered into the database on reported events. Thus, there was no way of completing the feedback loop to learn lessons gleaned from reporting incidents. The whole premise of the initiative of studying medical errors is to use data for trend analysis, to provide feedback, to educate and to improve systems (Berwick, 1996; Classen, Pestotnik, Evans, & Burke, 1991; Cullen et al., 1995). If the plan is to be valid and comparable throughout DoD, then the definitions of what constitutes adverse events have to made clear and unambiguous. Otherwise, events cannot be compared across facilities, because the parameters

may be different.

It is important that there be cultural change regarding blaming individuals for human errors. In fact, this is addressed in one of the standards for leadership by the Joint Commission, under LD.4.4, which calls for leaders to improve hospital performance, by adequate allocation of resources to measure, assess and improve performance (Busche, 2001; The Joint Commission, 2001 Hospital Accreditation Standards, 2001).

COL Judith Powers, the Army liaison for the PSWG, stated that it was important to separate the functions of reviewing cases for standard of care (peer review) when there has been a bad outcome and there is the propensity for litigation, from the day to day process of conducting a review of how processes are working, in the routine business of taking care of patients. This is akin to what physicians call "morbidity and mortality" reviews, where they discuss cases among themselves, usually on a departmental level, looking for ways to improve practice. COL Powers stated that the assessment and re-assessment of processes is not taking place in a proactive, positive way. In that sense, she was adamant that DD Form 2526 not be used for coding voluntarily reported errors, because it is a risk management document which is used in a malpractice scenario. This is justifiable, according to COL Powers, who stated that there is a need to separate the process of looking at peer review for determination of standard of care and the process of assessing how well we deliver health care. It is important to change the culture of blame. In order to do so, honest assessment of healthcare processes must be free of the risk of association with malpractice (personal communication, COL Powers, February 2001). The focus of patient safety in error reduction is to continuously review processes and make changes where indicated. From this perspective, patient safety is not interested in "naming names" and seeking punishment; their focus is to improve safety by improving processes. She reiterated that the peer review process should not cross into patient safety. The problem in small military healthcare facilities is that the groups of physicians who own the medical processes are the same group of people who conduct peer review. It is logistically difficult to keep two, separate processes going with two entirely different teams, with no cross interaction.

Currently, there are five MTFs that are participating in a pilot project for patient safety and were tasked to do a root cause analysis (RCA) upon completion of training at MEDCOM. They had the option of using a "near miss" that they experienced. Alternatively, the PSWG would have provided a scenario for them to analyze. To date, only two of the organizations have done an RCA, and they were marginally acceptable according to COL Powers. Although not a participant in the pilot project, WACH recently conducted a root cause analysis with regard to an incident involving bicillin. The incident is presented herewith because it is an excellent example of how a process was dissected, involving the principle participants.

The patient presented to the emergency room, complaining of 'flu-like symptoms. He was triaged as a non-urgent case to the fast track (minor illness clinic model). He was seen by a physician assistant (PA), who ordered intravenous fluids, and 1.2 M units of bicillin to be given via intravenous piggy-back (IVPB). During the infusion, the patient developed shortness of breath and an allergic reaction. He was immediately transferred to the emergency room for treatment and admitted for overnight observation. Subsequently, he recovered fully. In the subsequent risk assessment, the steps included the fact that the provider ordered the medication via an incorrect route (IV), and the LPN who administered the medication did not question the order. Factors included the lack of information about the appropriate route of administration for bicillin, in that it is only administered by an intramuscular route. The risk reduction strategies that will be adopted include the following. The PA will prepare a handout with the most commonly used drugs, addressing the correct route and dosage for each medication. All LPNs working in fast track will take the medication error reduction training program. A medication exam given during inprocessing will be posted in the competency based orientation (CBO) folder. The head nurse will familiarize the LPNs with the most common drugs used in fast track and will administer a department medication test. Further, there will be a minimum of two days of orientation when LPNs are assigned to the fast track. The number of patients per hour per provider will be reduced from 5 to 4 in order to avoid the risk of having too little time to do a proper assessment (personal communication, Kathy Dill, 9 March 2001).

The error of giving bicillin via the incorrect route is certainly not unique to WACH. There was a tragic incident, culminating in the death of a newborn in a Denver hospital in October 1996. A baby who was being treated for ostensible congenital syphilis not only received bicillin intravenously but also was given a 10-fold overdose. Not surprisingly, the punitive effort was swift and severe against the caregivers that were involved in the administration of the antibiotic. Three nurses were charged with criminally negligent homicide. However, there were abundant active and latent failures spread over several systems, to include patient information, communication, drug information, and drug labeling. The ultimate tragic irony is that the treatment, itself, was not indicated, as the mother no longer had active syphilis, only an antibody response from a previously treated episode. The ordering physician actually made the first error in the chain in not understanding the test results. However, once he had chosen to treat the infant, it was imperative that the decision be communicated appropriately, with correct follow-on processes by the pharmacy and the nurses who were responsible for administering the drug. Unfortunately, errors continued to cascade all along the pathway, including the miscalculation of an appropriate dose, a poorly labeled syringe and, finally, well-intentioned nurses who misunderstood that benzathine penicillin (bicillin) is not the same as penicillin G, which can be given intravenously. When the jury was presented the evidence of all the system failures, they returned a verdict of "not guilty" (Cohen & Smetzer, 2000; Laffel & Blumenthal, 1989).

Returning to the pilot safety program heretofore mentioned, the risk analysis that WACH conducted in its bicillin case appears to meet the tenets that COL Powers envisaged by the PSWG. Ultimately, COL Powers felt that the reason the MTFs participating in the pilot program did not do well was because PSWG had not articulated the expectations well, in terms of what they wanted to happen at the MTFs. Currently, patient safety program curriculum is in the process of undergoing reengineering.

Arnold H. Glasgow stated "One of the tests of leadership is the ability to recognize a problem before it becomes an emergency" (Jeffery, 2000, p 56). In fact, this statement succinctly summarizes the whole crux of the issue with regard to an error reduction initiative.

The proposal is to incorporate a systematic method for screening for problems before they become disasters. This is consistent with a proactive risk assessment that is now being promulgated by JCAHO. The idea is to select a high-risk process, identify its inherent risks and take steps to modify the process to improve safety and reduce errors (JCAHO Sentinel Event Alert, 2001). It is not necessary to have a "perfect" set of measures in order to start. What is suggested is to begin the process and to encourage the evolution. It will not necessarily be smooth, but it will be worthwhile.

At WACH, a delay in diagnosis or misdiagnosis and incorrect treatment are the two most common types of medical errors that end up as legitimate lawsuits. Parameters that may indicate that there is a problem with diagnosing a patient may include a patient with multiple, varied physical complaints, repeated out-patient and emergency room visits and visits to the emergency room following a scheduled out-patient appointment. Incorrect treatment is, unfortunately, readily understood in retrospect, as previously noted in the anecdotal cases. However, in a proactive sense, it may be possible to monitor treatment parameters in well-defined clinical practice guidelines (CPG) that WACH has adopted as standard practice. To date, CPGs on low back pain, asthma and diabetes are in effect. It is possible to review records pertaining to patients with these diagnoses in order to determine if the provider is compliant with the standards promulgated by the CPGs. Thus, incorrect treatment could be detected earlier rather than later and a change in treatment plan could be effected to bring it in concordance with the accepted standards. Otherwise, the provider would have to justify a deviation from the CPG by documenting his/her rationale for so doing. This would further serve to enforce adequate documentation. (Even when standard of care has been provided, if it is not documented, then it didn't happen. In fact, when the DoD loses a medical malpractice lawsuit, it is due, more often than not, to the fact that documentation was poor or non-existent (personal communication, Cary Collins, hospital lawyer for WACH, October 2000).

The proposal is to compose two to four CHCS ad hoc reports that would address the above-mentioned issues of delay in diagnosis and incorrect treatment. The perspective would be

proactive, rather than simply reactive and retroactive. This type of error reduction initiatives does not rely on reporting. There are some pre-existing CHCS ad hoc reports that may already serve the purpose for screening for multiple visits. A weekly threshold of two or more visits may prove to be a sensitive indicator. If patients who fit this category have records that indicate there may be a problem with diagnosis, then it will behoove WACH to assign a case manager. Another CHCS ad hoc report can sort patients by diagnosis and evaluate what labs have been drawn, which medications prescribed, and how often visits occur, to determine if care is in compliance with adopted CPGs.

With regard to medication errors, WACH will be participating in additional initiatives, to include a medication error information reporting system that is promulgated by the United States Pharmacopeial Convention, Inc. and is called MedMARx™. This will not only enhance the opportunity to look at circumstances that have the capacity to cause error, but will serve as a benchmark against other like-sized hospitals, both military and civilian. The marketing of the process will be done through the medical use committee as well as the risk management/patient safety committee. In addition, WACH has purchased an interactive computer based training course for medication error reduction which will be implemented for use in 2001 (Abbey Associates, 2000).

As Henry Ford said, "Don't find a fault. Find a remedy" (Jeffery, 2000, p 156) The issue is not one of not uncovering or finding faults, rather it is in studying faults to seek remedies. This work suggests that there are ways to achieve this goal of error reduction by anticipating where the faults may lie. Automated solutions are preferable to those reliant on voluntary participation. There is a method of screening for faults or medical errors, and, once finding them, taking appropriate interventional action to change the outcome.

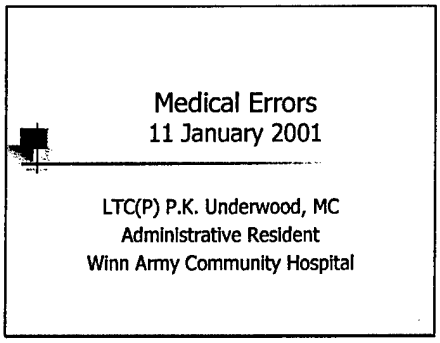
Although limited in scope, this project showed that it is better to rely on using automated types of initiatives to reduce error, rather than relying on voluntary incentives. In summary, my opinion is that DoD should not rely solely on reporting of "near misses" and medical errors. The reasons for my argument have been presented. The strongest evidence is that reporting does not

capture the whole of the picture; rather, it only reflects the proverbial "tip of the iceberg". While reporting should be encouraged, it should not be the sole platform on which decisions or reports about performance should be made. I believe the error reduction initiative should be a multifaceted approach. While including and encouraging reporting, it should actively pursue other systematic, objective means of gathering data. One of those means has been introduced; using CHCS ad hoc reporting in a proactive way to intervene in two areas known to give rise to legitimate lawsuits; i.e. delay in diagnosis/misdiagnosis and incorrect treatment. With regard to medication errors, which make up approximately 20% of all reported errors, there is even a greater role for automated system to systematically uncover errors. If the system can be made safer through automated efforts, then the need for voluntary, independent human action can be reduced.

Stephen R. Covey said, "It is not what others do or even our own mistakes that hurt us the most; it is our response to those things. Our response to any mistake affects the quality of the next moment. It is important to immediately admit and correct our mistakes so that they have no power over that next moment and we are empowered again" (Covey, 1989, p. 91). Healthcare organizations must take heed of the message that Mr. Covey has conveyed. Mistakes are an inevitable part of human experience. An organization can grow and succeed in providing a safer environment for its patients, when the lesson is learned that instead of being reviled, mistakes provide an opportunity to improve and alter processes (Bagian et al., 2001; Bosk, 1979). Dennis S. O'Leary, the president of JCAHO, summed it best when he stated "In the end, what we most need is a characteristic not described by Hippocrates-the ability of care givers to admit and accept fallibility" (Joint Commission Resources (Brochure), 2001, p.12). The real challenge for health care providers, be they nurses, physicians, pharmacists or intensivists, is to make it difficult to make mistakes (Enright et al., 2000). Ultimately, this will happen when healthcare providers work to change the paradigm of blame and turn their attention to improving processes.

Appendix A
Lecture on Medical Errors
Presented on 11 January 2001

1



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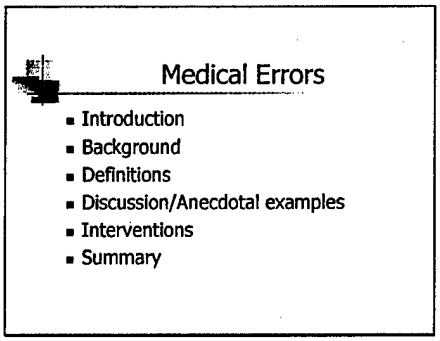

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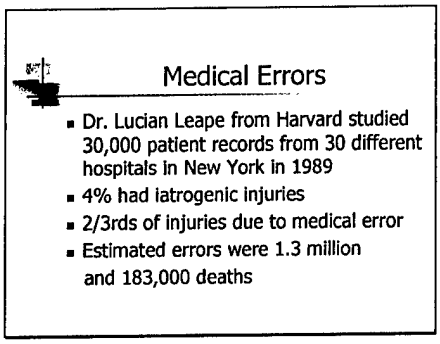
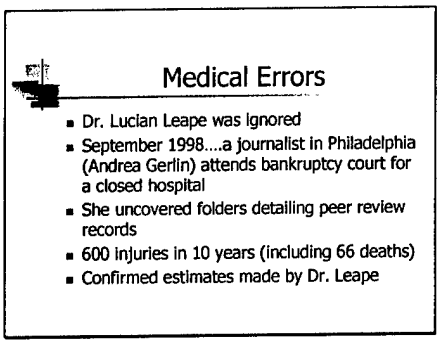
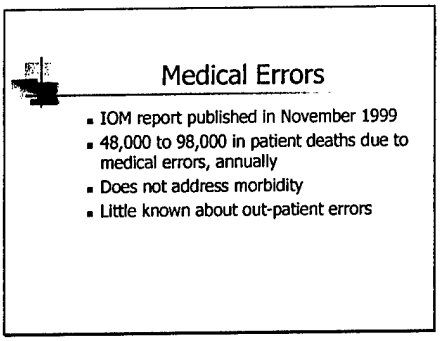

Medical Errors
Dr. Lucian Leape from Harvard studied 30,000 patient records from 30 different hospitals in New York in 1989
4% had iatrogenic injuries
2/3rds of injuries due to medical error
Estimated errors were 1.3 million and 183,000 deaths

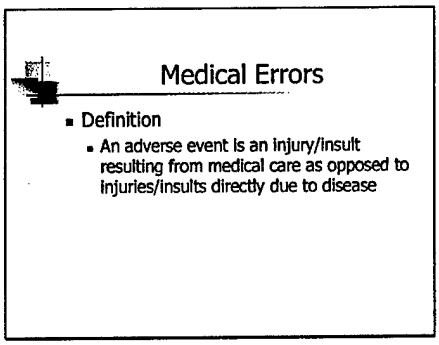
4


Medical Errors
Dr. Lucian Leape was ignored
September 1998....a journalist in Philadelphia (Andrea Gerlin) attends bankruptcy court for a closed hospital
She uncovered folders detailing peer review records
600 injuries in 10 years (including 66 deaths)
Confirmed estimates made by Dr. Leape

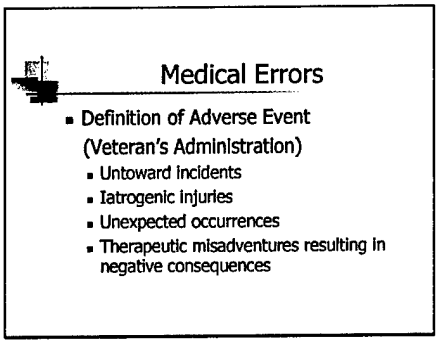
5


Medical Errors
IOM report published in November 1999
48,000 to 98,000 in patient deaths due to medical errors, annually
Does not address morbidity
Little known about out-patient errors

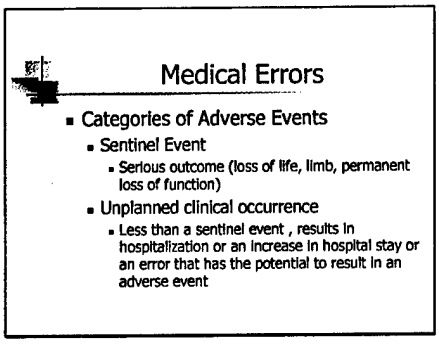
6


Medical Errors
Definition
An adverse event is an injury/insult resulting from medical care as opposed to injuries/insults directly due to disease

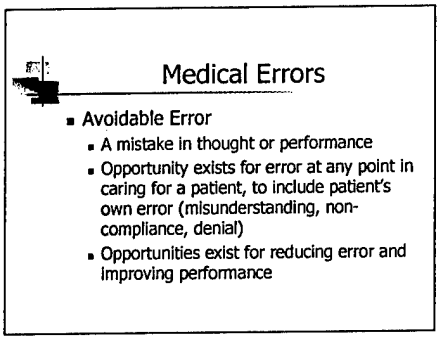
7


Medical Errors
Definition of Adverse Event (Veteran's Administration)
Untoward incidents
Iatrogenic injuries
Unexpected occurrences
Therapeutic misadventures resulting in negative consequences

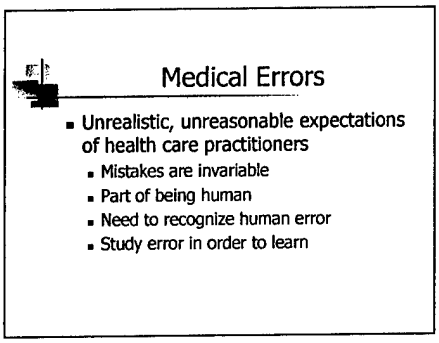
8


Medical Errors
Categories of Adverse Events
Sentinel Event
Serious outcome (loss of life, limb, permanent loss of function)
Unplanned clinical occurrence
Less than a sentinel event , results in hospitalization or an increase in hospital stay or an error that has the potential to result in an adverse event

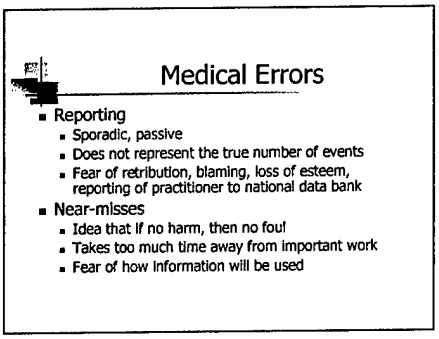
9


Medical Errors
Avoidable Error
A mistake in thought or performance
Opportunity exists for error at any point in caring for a patient, to include patient's own error (misunderstanding, non-compliance, denial)
Opportunities exist for reducing error and improving performance

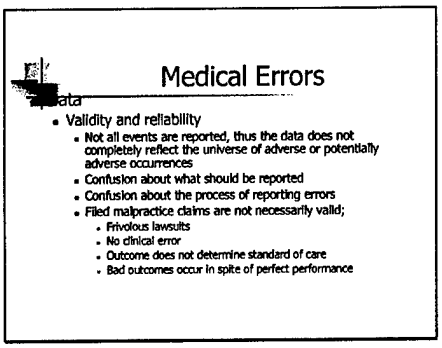
10


Medical Errors
Unrealistic, unreasonable expectations of health care practitioners
Mistakes are invariable
Part of being human
Need to recognize human error
Study error in order to learn

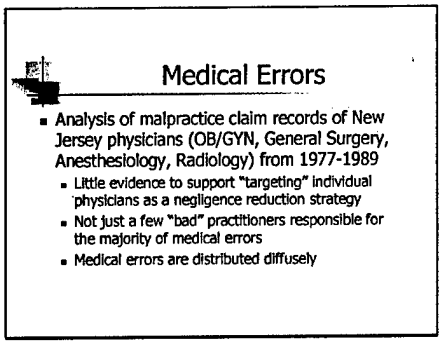
11


Medical Errors
Reporting
Sporadic, passive
Does not represent the true number of events
Fear of retribution, blaming, loss of esteem, reporting of practitioner to national data bank
Near-misses
Idea that if no harm, then no foul
Takes too much time away from important work
Fear of how information will be used

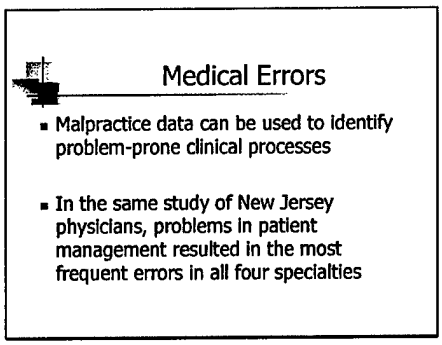
12


Medical Errors
ata
Validity and reliability
Not all events are reported, thus the data does not completely reflect the universe of adverse or potentially adverse occurrences
Confusion about what should be reported
Confusion about the process of reporting errors
Filed malpractice claims are not necessarily valid;
Frivolous lawsuits
No clinical error
Outcome does not determine standard of care
Bad outcomes occur in spite of perfect performance

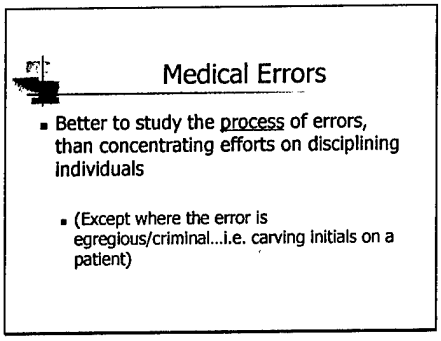
13


Medical Errors
Analysis of malpractice claim records of New Jersey physicians (OB/GYN, General Surgery, Anesthesiology, Radiology) from 1977-1989
Little evidence to support "targeting" individual physicians as a negligence reduction strategy
Not just a few "bad" practitioners responsible for the majority of medical errors
Medical errors are distributed diffusely

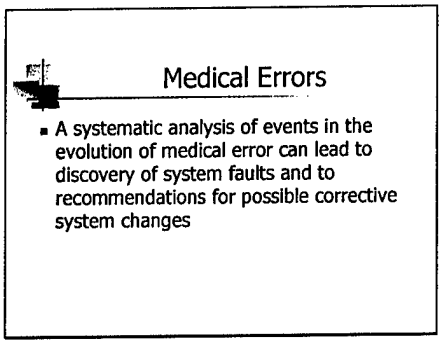
14


Medical Errors
Malpractice data can be used to identify problem-prone clinical processes
In the same study of New Jersey physicians, problems in patient management resulted in the most frequent errors in all four specialties

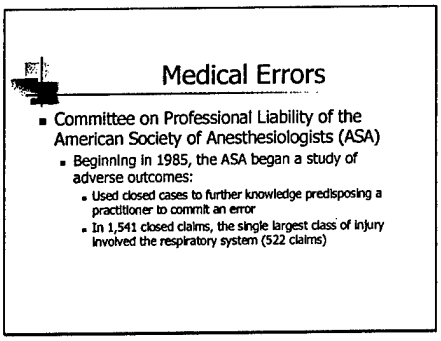
15


Medical Errors
Better to study the process of errors, than concentrating efforts on disciplining individuals
(Except where the error is egregious/criminal...i.e. carving initials on a patient)

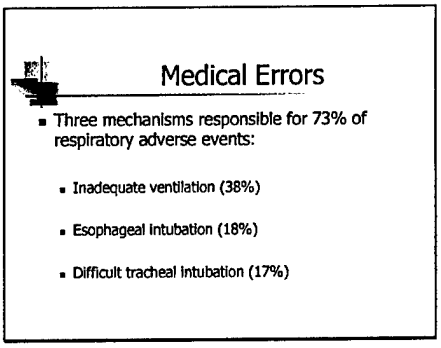
16


Medical Errors
A systematic analysis of events in the evolution of medical error can lead to discovery of system faults and to recommendations for possible corrective system changes

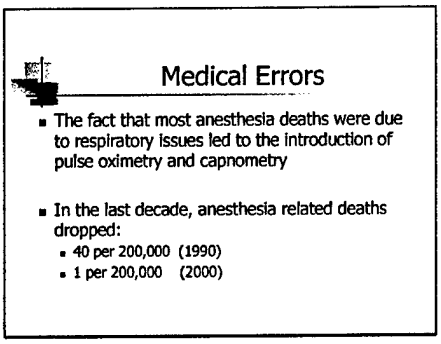
17


Medical Errors
Committee on Professional Liability of the American Society of Anesthesiologists (ASA)
Beginning in 1985, the ASA began a study of adverse outcomes:
Used closed cases to further knowledge predisposing a practitioner to commit an error
In 1,541 closed claims, the single largest class of injury involved the respiratory system (522 claims)

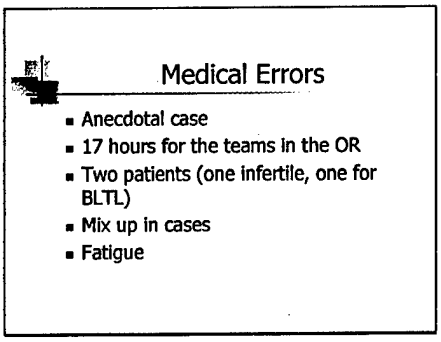
18


Medical Errors
Three mechanisms responsible for 73% of respiratory adverse events:
Inadequate ventilation (38%)
Esophageal intubation (18%)
Difficult tracheal intubation (17%)

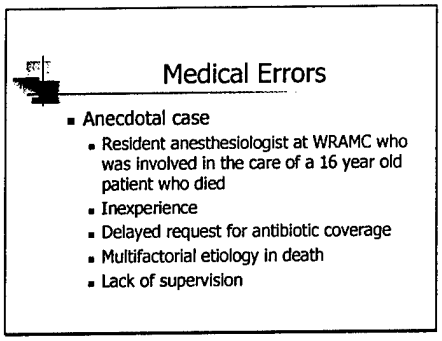
19


Medical Errors
The fact that most anesthesia deaths were due to respiratory issues led to the introduction of pulse oximetry and capnometry
In the last decade, anesthesia related deaths dropped:
40 per 200,000 (1990)
1 per 200,000 (2000)

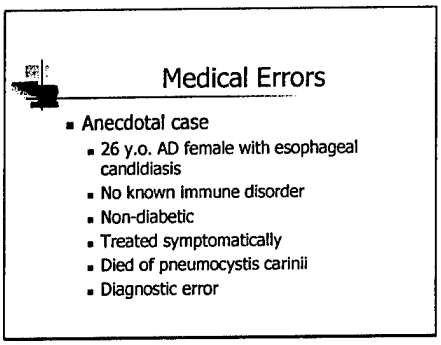
20


Medical Errors
Anecdotal case
17 hours for the teams in the OR
Two patients (one infertile, one for BLTL)
Mix up in cases
Fatigue

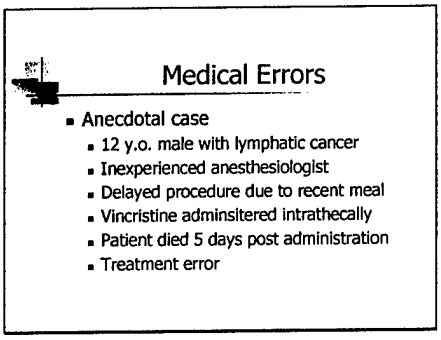
21


Medical Errors
Anecdotal case
Resident anesthesiologist at WRAMC who was involved in the care of a 16 year old patient who died
Inexperience
Delayed request for antibiotic coverage
Multifactorial etiology in death
Lack of supervision

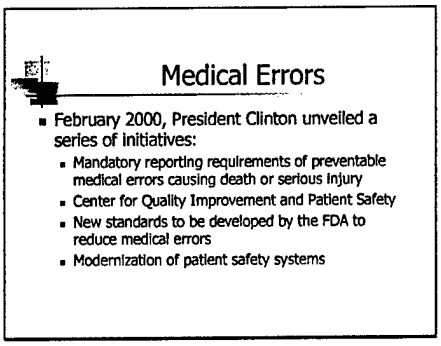
22


Medical Errors
Anecdotal case
26 y.o. AD female with esophageal candidiasis
No known immune disorder
Non-diabetic
Treated symptomatically
Died of pneumocystis carinii
Diagnostic error

23


Medical Errors
Anecdotal case
12 y.o. male with lymphatic cancer
Inexperienced anesthesiologist
Delayed procedure due to recent meal
Vincristine adminsitered intrathecally
Patient died 5 days post administration
Treatment error

24


Medical Errors
February 2000, President Clinton unveiled a series of initiatives:
Mandatory reporting requirements of preventable medical errors causing death or serious injury
Center for Quality Improvement and Patient Safety
New standards to be developed by the FDA to reduce medical errors
Modernization of patient safety systems

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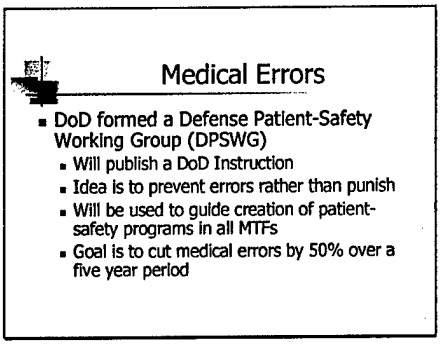
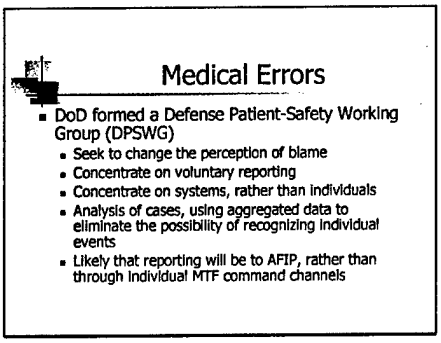

Medical Errors
DoD formed a Defense Patient-Safety Working Group (DPSWG)
Will publish a DoD Instruction
Idea is to prevent errors rather than punish
Will be used to guide creation of patient-safety programs in all MTFs
Goal is to cut medical errors by 50% over a five year period

26


Medical Errors
DoD formed a Defense Patient-Safety Working Group (DPSWG)
Seek to change the perception of blame
Concentrate on voluntary reporting
Concentrate on systems, rather than individuals
Analysis of cases, using aggregated data to eliminate the possibility of recognizing individual events
Likely that reporting will be to AFIP, rather than through individual MTF command channels

27

Medical Errors

- Database initiated at WACH in August 1996
  - Leaving against medical advice
  - Patient/visitor falls
  - Failure to administer medication as ordered
  - Failure to adhere to hospital policy/procedures
  - Medication errors accounted for 20% of all reports

28

It is important that the patient understands how to take the medication

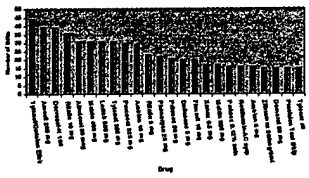
29

Medical Errors

- Intervention to reduce medical error at WACH
  - Taking only those drugs for which there were 15 or more edits (24 items)
  - Create default prescriptions
  - Physician can choose rather than having to type

30

Medical Errors



31

Medical Errors

- Summary
  - Mistakes are inevitable
  - Mistakes are made by all health care providers...not just incompetent ones
  - Medicine is a hazardous "industry"
  - Error is part of medical practice
  - Medicine is not exact
  - Expectations are high and often unrealistic

32

Medical Errors

- Summary
  - Reluctance to report errors
  - Mistakes are usually due to a chain of events
  - Factors involved can include:
    - Fatigue
    - Inexperience/Lack of supervision
    - Diagnostic error
    - Treatment error

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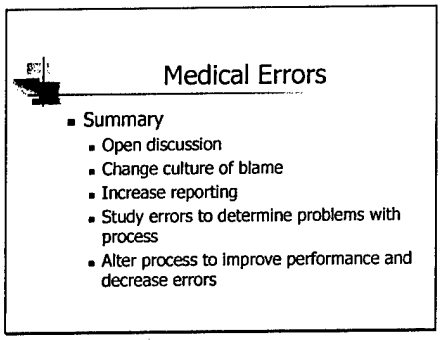
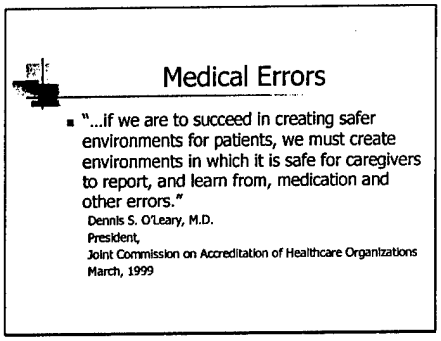

Medical Errors
Summary
Open discussion
Change culture of blame
Increase reporting
Study errors to determine problems with process
Alter process to improve performance and decrease errors

34


Medical Errors
"...if we are to succeed in creating safer environments for patients, we must create environments in which it is safe for caregivers to report, and learn from, medication and other errors."
Dennis S. O'Leary, M.D.
President,
Joint Commission on Accreditation of Healthcare Organizations
March, 1999

Appendix B
Codes used in Risk Management Database

01 **Standard of care met; no problem identified**

100 **Medical Record Review**
- 101 No/Incomplete documentation
- 102 Delinquent medical record
- 103 Unable to locate record
- 104 Test results not in record
- 105 Failure to obtain informed consent
- 106 Inappropriate documentation of do not resuscitate (DNR) orders
- 107 Failure to renew DNR within 72 hours
- 108 Inappropriate alteration of the medical record
- 109 No/Inadequate informed consent

200 **Surgical Case Review**
- 201 Return to surgery during same admission
- 202 Failure of anesthesia technique
- 203 Failure of surgical technique
- 204 Excessive post-op hemorrhage
- 205 Post-op infection
- 206 Tissue not sent to pathology
- 207 Pathology report does not support pre-op diagnosis
- 208 Retained foreign body
- 209 Operating on wrong body part/patient
- 210 Delay in surgery
- 211 Improper management of a surgical patient
- 212 Negligent prenatal care
- 213 Improperly performed vaginal delivery
- 214 Improperly performed Caesarian section
- 215 Negligent delay in delivery
- 216 Improperly managed labor
- 217 Failure to identify fetal distress
- 218 Failure to identify failure to progress
- 219 Failure of anesthesia to obtain patient history and physical (H & P)
- 220 Anesthesia failure to monitor patient
- 221 Improper choice of anesthesia agent
- 222 Improper use of anesthesia equipment
- 223 Improper intubation of patient
- 224 Improper positioning of patient
- 225 Inadequate post-op care/follow -up
- 226 Patient injury due to equipment user error
- 227 Failure to prep patient
- 228 Surgical aspiration
- 229 Pneumothorax, complication of treatment

230 Inappropriate needle localization/biopsy
231 Incorrect post-op instrument count
232 Break in sterile field during procedure
233 Failed regional anesthesia
234 Adverse reaction to anesthesia
235 Injury to infant during delivery
236 Fetal demise
237 Precipitous delivery
238 Unattended delivery

300 Pharmacy & Therapeutics/Drug Utilization Review

301 Medication error
302 Adverse drug reaction
303 Inappropriate drug use
304 Failure to order appropriate medication
305 Failure to administer medication as ordered
306 Failure to monitor medication
307 Wrong medication administered
308 Wrong dosage administered
309 Failure in administration technique
310 Failure to recognize known drug allergies
311 Patient refused medication
312 Failure to re-order medication upon transfer
313 Narcotic count wrong
314 Improperly filled physician's order for in-patient
315 Improperly labeled prescription
316 Prescription filled with wrong medication
317 Prescription filled with wrong strength of right medication
318 Dispensing prescription to wrong patient
319 Inappropriate prescription written, filled and dispensed
320 Patient self-overdose
321 Patient non-compliance with medication
322 Medication order transcription error
323 Wrong intravenous fluid infused
324 Medication administered to wrong patient
325 Failure to order indicated test prior to ordering medication
326 Transcription error

400 Pathology Review

401 Specimen labeled incorrectly
402 Inappropriate interpretation of a lab test
403 Excessive delay in performing a test
404 Unable to locate specimen
405 Unable to locate test results
406 Failure to notify when panic values are exceeded
407 Inappropriate performance of a test
408 Specimen collected from wrong patient

409 Delay in specimen arriving in the lab
410 Information with specimen incomplete/illegible

500 Unusual Occurrences

501 Fall
502 Needle stick
503 Against Medical Advice
504 Elopement/walk-out
505 Equipment failure
506 IV complication
507 Exposure to blood/body fluid splash
508 Visitor injury
509 Patient injury (self-injury)
510 Staff injury (self-injury)
511 Inappropriate behavior
512 Self extubation
513 Staff injured by patient
514 Patient injured by staff
515 Property loss/damage
516 Inadequate staffing
517 Patient refuses treatment
518 Injury due to user error of equipment
519 Risk management report delayed longer than 48 hours
520 Patient non-compliant with treatment
521 Patient injury/correct use of equipment
522 Arterial line complication
523 Workman's Compensation claim
524 Diet variance
525 Safety precautions inadequate in construction area
526 Failure to inspect/monitor
527 Improper maintenance
528 Suicide attempt
529 Suicide
530 Restraints

600 Practice Variance

601 Readmission within 30 days for same diagnosis
602 Admission for complication of outpatient care
603 Transfer to higher level of care
604 Organ failure not present on admission
605 Delay in diagnosis
606 Delay in treatment
607 Inappropriate referral
608 Inappropriate transfer
609 Inadequate assessment
610 Unexpected death
611 No/Insufficient follow-up

612 Wrong diagnosis
613 Delinquent test results
614 Incorrect transcription of orders
615 Failure to diagnose
616 Improper interpretation of a diagnostic test
617 Failure to treat
618 Improper management of the course of treatment
619 Improper performance of a procedure
620 Failure to seek consultation
621 Inappropriate behavior of the clinician
622 Breach of confidentiality
623 Failure to adhere to policy/procedure
624 Failure to monitor patient
625 Inappropriate management of a code
626 Conscious sedation variation
627 Inappropriate DNR/living will documentation
628 Inappropriate use of restraints
629 Seclusion
630 Failure to follow up on abnormal test results
631 Natural course of a disease process
632 Inappropriate psychological
633 Inappropriate inservice/use of equipment
634 Transport delay
635 Dead on arrival (DOA) in the emergency room
636 Multiple visits for the same complaint
637 Inadequate supervision
638 Failure to respond to a page in a timely manner

700 Radiation Therapy

701 Exposure while pregnant
702 Inappropriate interpretation of an x-ray study
703 Inappropriate interpretation of a computerized tomography (CT) scan
704 Inappropriate interpretation of an ultrasound
705 Failure to notify health care provider of abnormal findings
706 Films filed without interpretation
707 Unable to locate patient's test results
708 Missed fracture
709 Missed mass/lesion
710 Missed obstruction
711 Missed pneumonia/congestive heart failure (CHF)
712 Missed intrauterine pregnancy (IUP)
713 Missed ectopic pregnancy
714 Excessive delay in the performance of a study
715 Failure to perform ordered procedure

800 Blood Utilization Review

801 Failure to order appropriate blood products
802 Failure to ensure compatibility
803 Specimen labeled incorrectly
804 Failure to monitor during transfusion
805 Improper handling/dispensing of blood products
806 Adverse reaction to a transfusion
807 Failure to follow blood transfusion policy
808 Wrong type of blood dispensed
809 Positive HIV test following a transfusion

900 Utilization Review

901 Excessive length of stay
902 Unnecessary lab test
903 Unnecessary x-ray procedure
904 Unnecessary procedure
905 Unnecessary drug usage
906 Unnecessary admission
907 Unnecessary transfer
908 Inappropriate deviation from a clinical practice guideline
909 (Omitted)
910 Inappropriate blood usage
911 Inappropriate use of staff
912 Sole provider patients with complex medical problems
913 Sole provider patients abusing controlled drugs
914 Sole provider patients with malpractice claims

Appendix C
Act or Omission Codes from DD Form 2526

Diagnosis Related

010 Failure to diagnose
020 Wrong diagnosis
030 Improper performance of test
040 Unnecessary diagnostic test
050 Delay in diagnosis
060 Failure to obtain consent/lack of informed consent
90 Diagnosis related, not otherwise classified (NOC)

Anesthesia Related

110 Failure to complete patient assessment
120 Failure to monitor
130 Failure to test equipment
140 Improper choice of anesthesia agent or equipment
150 Improper technique/induction
160 Improper equipment use
170 Improper intubation
180 Improper positioning
185 Failure to obtain consent/lack of informed consent
190 Anesthesia related (NOC)

Surgery Related

210 Failure to perform surgery
220 Improper positioning
230 Retained foreign body
240 Wrong body part
250 Improper performance of surgery
260 Unnecessary surgery
270 Delay in surgery
280 Improper management of surgical patient
285 Failure to obtain consent for surgery/lack of informed consent
290 Surgery related (NOC)

Medication Related

305 Failure to order appropriate medication
310 Wrong medication ordered
315 Wrong dosage ordered of correct medication
320 Failure to instruct on medication
325 Improper management of medication program
330 Failure to obtain consent for medication/lack of informed consent
340 Medication error (NOC)
350 Failure to medicate
355 Wrong medication administered
360 Wrong dosage administered

365 Wrong patient
370 Wrong route
380 Improper technique
390 Medication administration related (NOC)

Intravenous and Blood Products Related
411 Failure to monitor
420 Wrong solution
430 Improper performance
440 IV related (NOC)
450 Failure to insure contamination free
460 Wrong type
470 Improper administration
480 Failure to obtain consent/lack of informed consent
490 Blood product related (NOC)

Obstetrics Related
505 Failure to manage pregnancy
510 Improper choice of delivery method
520 Improperly performed vaginal delivery
525 Improperly performed C-section
530 Delay in delivery (induction or surgery)
540 Failure to obtain consent/lack of informed consent
550 Improperly managed labor (NOC)
555 Failure to identify/treat fetal distress
560 Delay in treatment of fetal distress (i.e. identified but treated in an untimely manner)
570 Retained foreign body/vaginal/uterine
580 Abandonment
590 Wrongful life/birth
590 Obstetrics related (NOC)

Treatment Related
610 Failure to treat
620 Wrong treatment/procedure performed (also improper choice)
630 Failure to instruct patient on self care
640 Improper performance of a treatment/procedure
650 Improper management of course of treatment
660 Unnecessary treatment
665 Delay in treatment
670 Premature end of treatment (also abandonment)
675 Failure to supervise treatment/procedure
680 Failure to obtain consent for treatment/lack of informed consent
685 Failure to refer/seek consultation
690 Treatment related (NOC)

Monitoring

710 Failure to monitor
720 Failure to respond to patient
730 Failure to report on patient condition
790 Monitoring related (NOC)

Biomedical Equipment/Product Related

810 Failure to inspect/monitor
820 Improper maintenance
830 Improper use
840 Failure to respond to warning
850 Failure to instruct patient on use of equipment/product
860 Malfunction/failure
890 biomedical equipment/product related (NOC)

Miscellaneous

910 Inappropriate behavior of clinician (i.e. sexual misconduct allegation, assault)
920 Failure to protect third parties (i.e. failure to warn/protect from violent patient behavior)
930 Breach of confidentiality/privacy
940 Failure to maintain appropriate infection control
950 Failure to follow institutional policy or procedure
960 Other (provide detailed written description)
990 Failure to review provider performance

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Table 1

Statistical Results of Comparison of Mean Number of Reports Between Fiscal Years 2000 and 2001 for the Months of October through February

Month	*Mean Number Reports FY 00*	*Mean Number Reports FY 01*	*t statistic*	*One -tail p value*	*Two-tail p value*	*Statistical significance*
October	3.8	3.4	0.272	0.399	0.799	NS
November	2	4.4	-1.530	0.100	0.201	NS
December	1.8	2.4	-1	0.187	0.374	NS
January	4.6	3.6	0.745	0.249	0.497	NS
February	6.2	2.4	2.179	0.047	0.095	Significant for one-tail p value
October-February	18.4	16.2	0.432	0.344	0.688	NS

Table 2

Statistical Results of Comparison of Mean Number of Pharmacy Edits Before and After Intervention

Mean Number of Pharmacy Edits (Initial)	*Mean Number of Pharmacy Edits (Post-Intervention)*	*t statistic*	*One-tail p value*	*Two-tail p value*	*Statistical significance*
24.54	10.12	6.121	1.518×10^{-6}	3.036×10^{-6}	Highly Significant

Table 3

Types of Medication Errors

Type of Medication Error	*Number/Percentage of Total*
Failure to administer medication as ordered	102 (36.5%)
Wrong medication administered	32 (11.5%)
Prescription filled with wrong medication	30 (10.8%)
Wrong dosage administered	16 (5.7%)
Filled with wrong strength of right medication	14 (5%)
Wrong IV fluid infused	12 (4.3%)
Medication order transcription error	11 (3.9%)
Failure in administration technique	9 (3.2%)
Medication error (not otherwise specified)	9 (3.2%)
Adverse drug reaction	8 (2.9%)
Improperly filled doctor's order for in-patient	6 (2.2%)
Improperly labeled prescription	5 (1.8%)
Narcotic count wrong	5 (1.8%)
Failure to monitor medication	3 (1.1%)
Failure to order appropriate medication	3 (1.1%)
Inappropriate script written, filled & dispensed	3 (1.1%)
Dispensing prescription to wrong patient	3 (1.1%)
Patient non-compliance with medication	2 (0.72%)
Inappropriate drug use	2 (0.72%)
Failure to recognize known drug allergies	2 (0.72%)

Patient self-overdose	1 (0.36%)
Failure to order indicated test prior to ordering medication	1 (0.36%)
TOTAL	279

Figure 1.

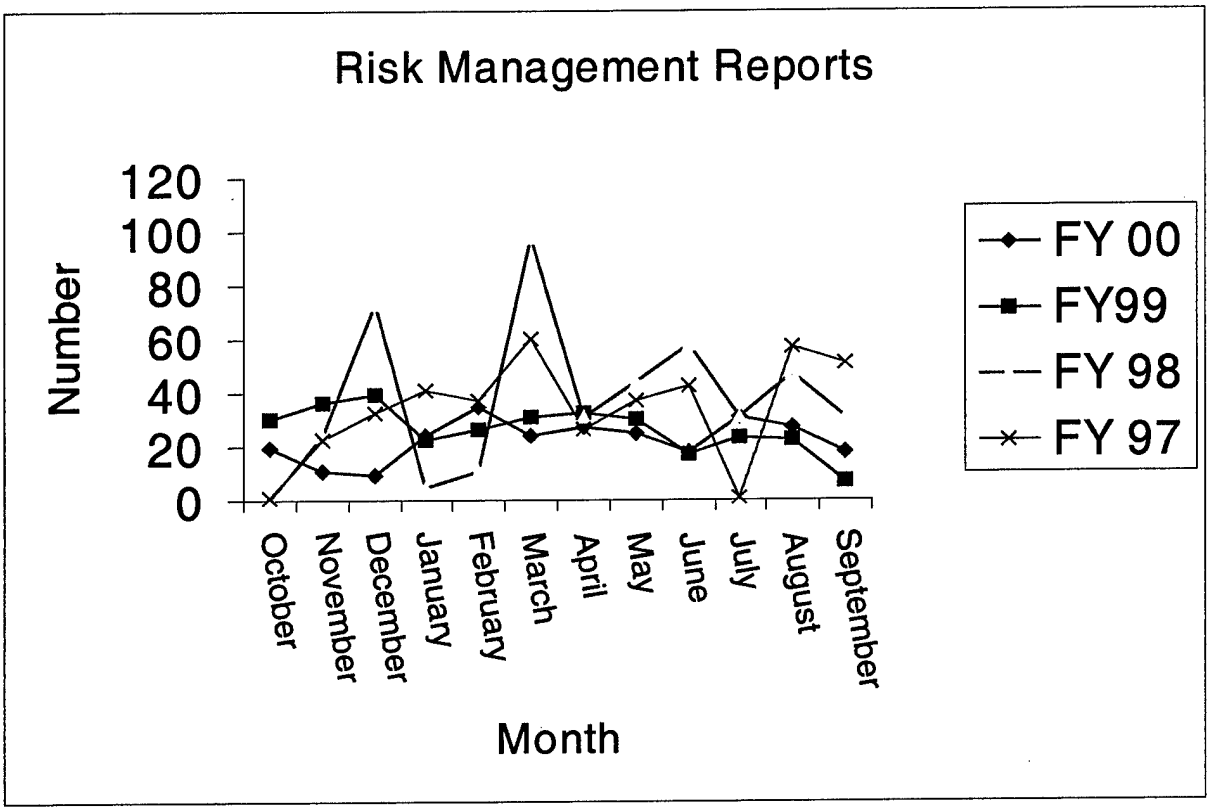

Risk Management Reports
Number
120
100
80
60
40
20
0
October
November
December
January
February
March
April
May
June
July
August
September
Month
FY 00
FY99
FY 98
FY 97

Figure 2.

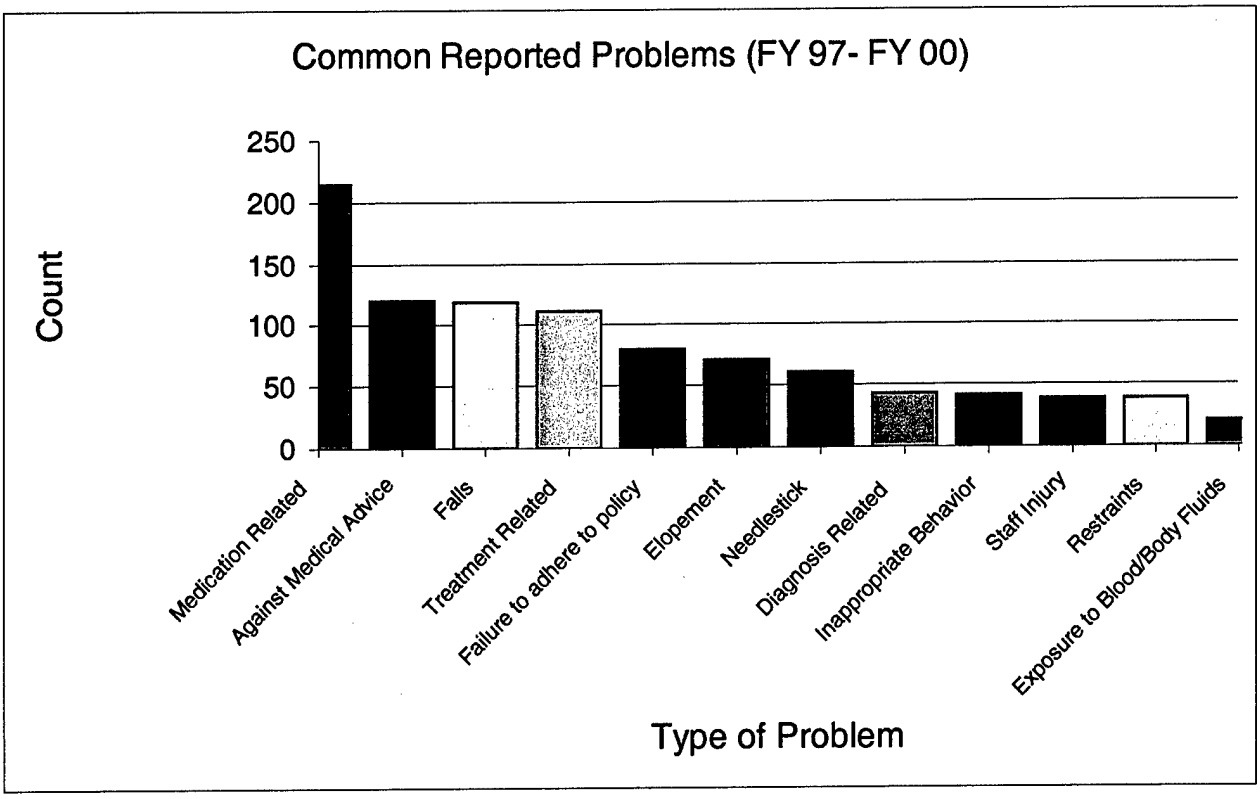

Common Reported Problems (FY 97- FY 00)
Count
250
200
150
100
50
0
Medication Related
Against Medical Advice
Falls
Treatment Related
Failure to adhere to policy
Elopement
Needlestick
Diagnosis Related
Inappropriate Behavior
Staff Injury
Restraints
Exposure to Blood/Body Fluids
Type of Problem

Figure 3.

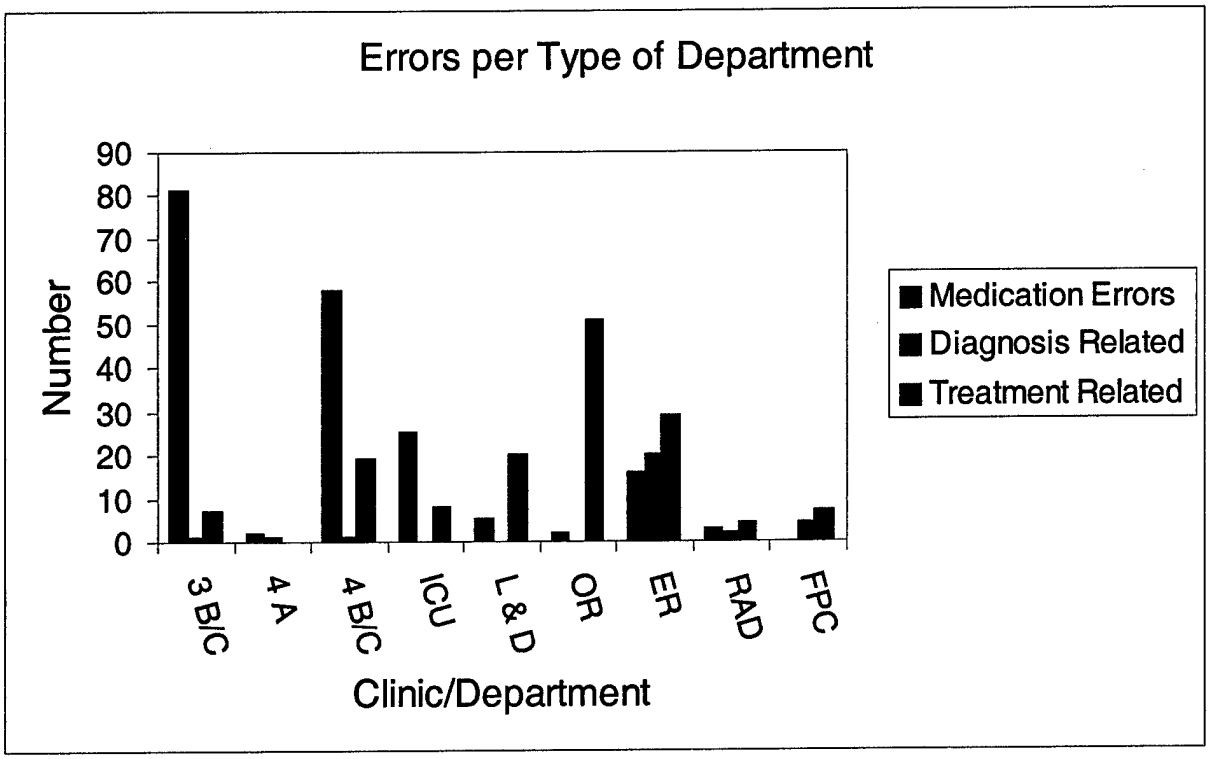

Errors per Type of Department
Number
90
80
70
60
50
40
30
20
10
0
3 B/C
4 A
4 B/C
ICU
L & D
OR
ER
RAD
FPC
Clinic/Department
Medication Errors
Diagnosis Related
Treatment Related

Figure 4.

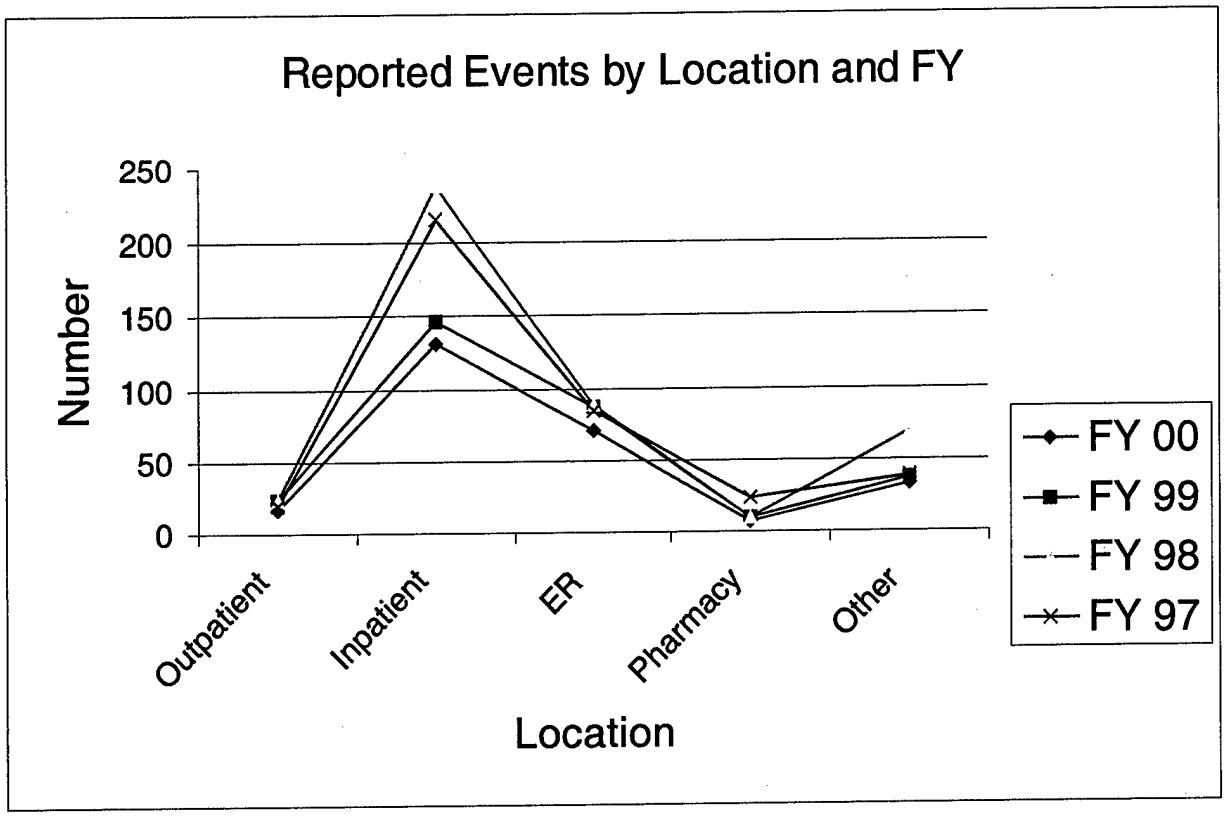

Reported Events by Location and FY
250
200
150
100
50
0
Number
Outpatient
Inpatient
ER
Pharmacy
Other
Location
FY 00
FY 99
FY 98
FY 97

Figure 5.

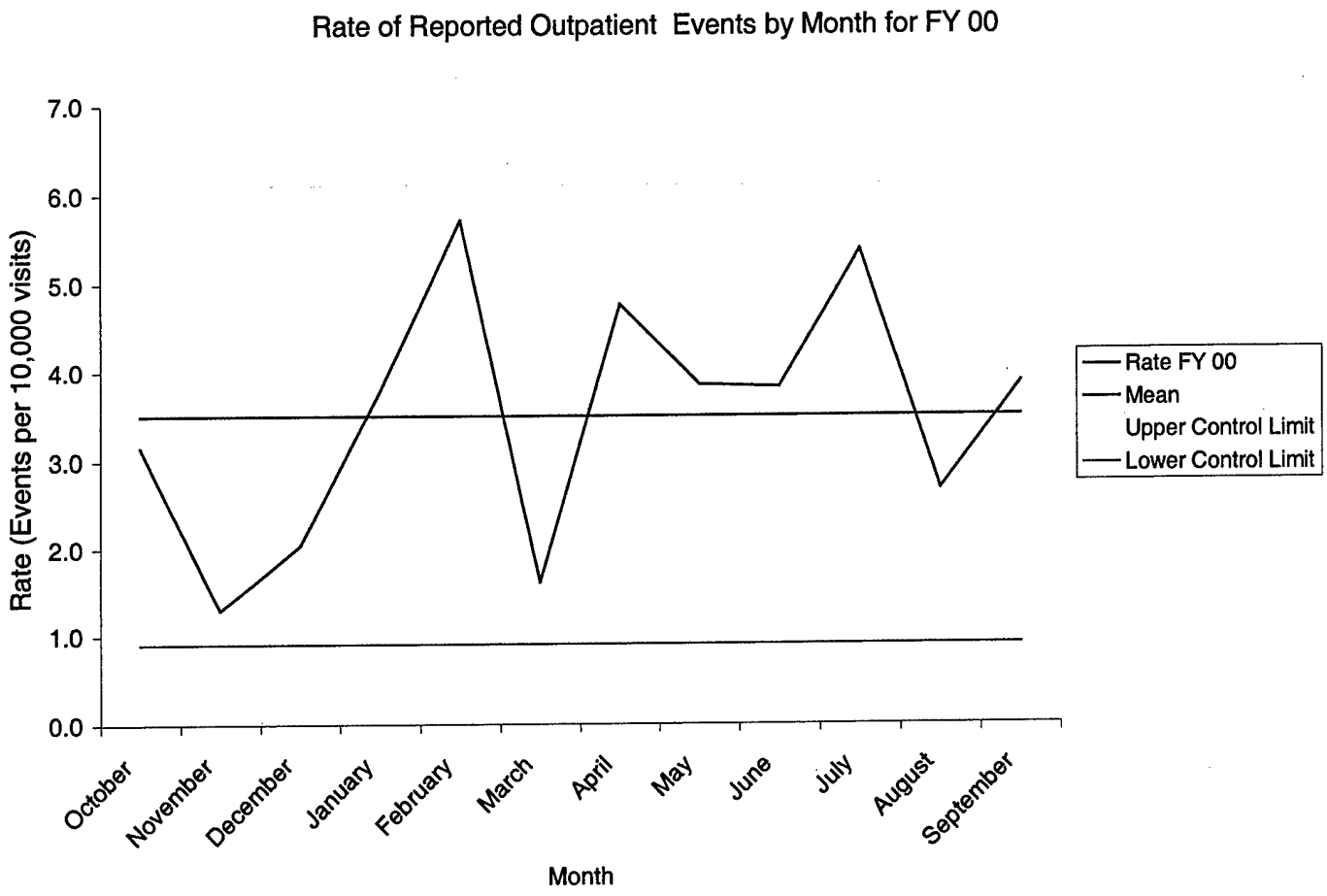

Rate of Reported Outpatient Events by Month for FY 00
Rate (Events per 10,000 visits)
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
October
November
December
January
February
March
April
May
June
July
August
September
Month
Rate FY 00
Mean
Upper Control Limit
Lower Control Limit

Figure 6.

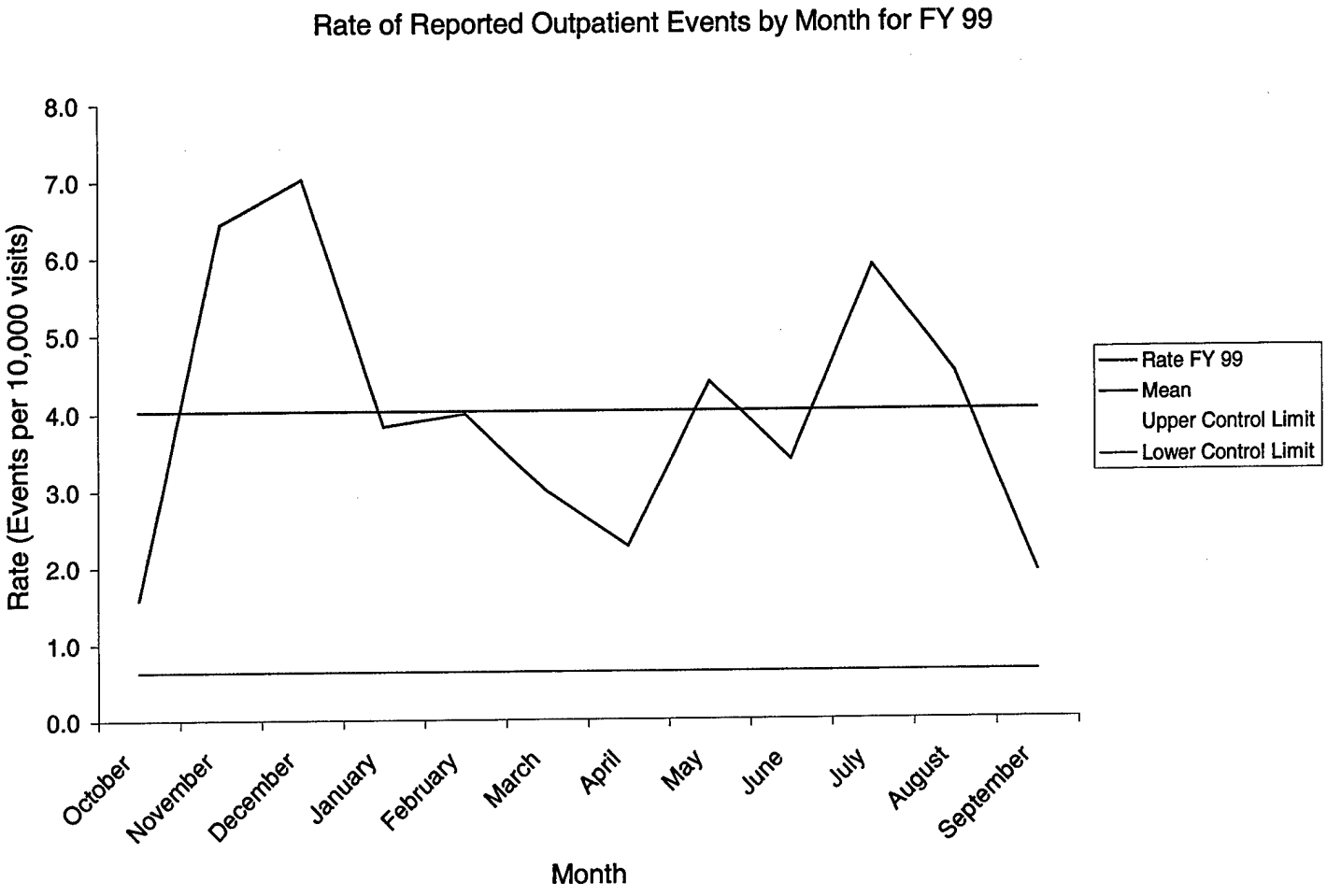

Rate of Reported Outpatient Events by Month for FY 99
Rate (Events per 10,000 visits)
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
October
November
December
January
February
March
April
May
June
July
August
September
Month
Rate FY 99
Mean
Upper Control Limit
Lower Control Limit

Figure 7.

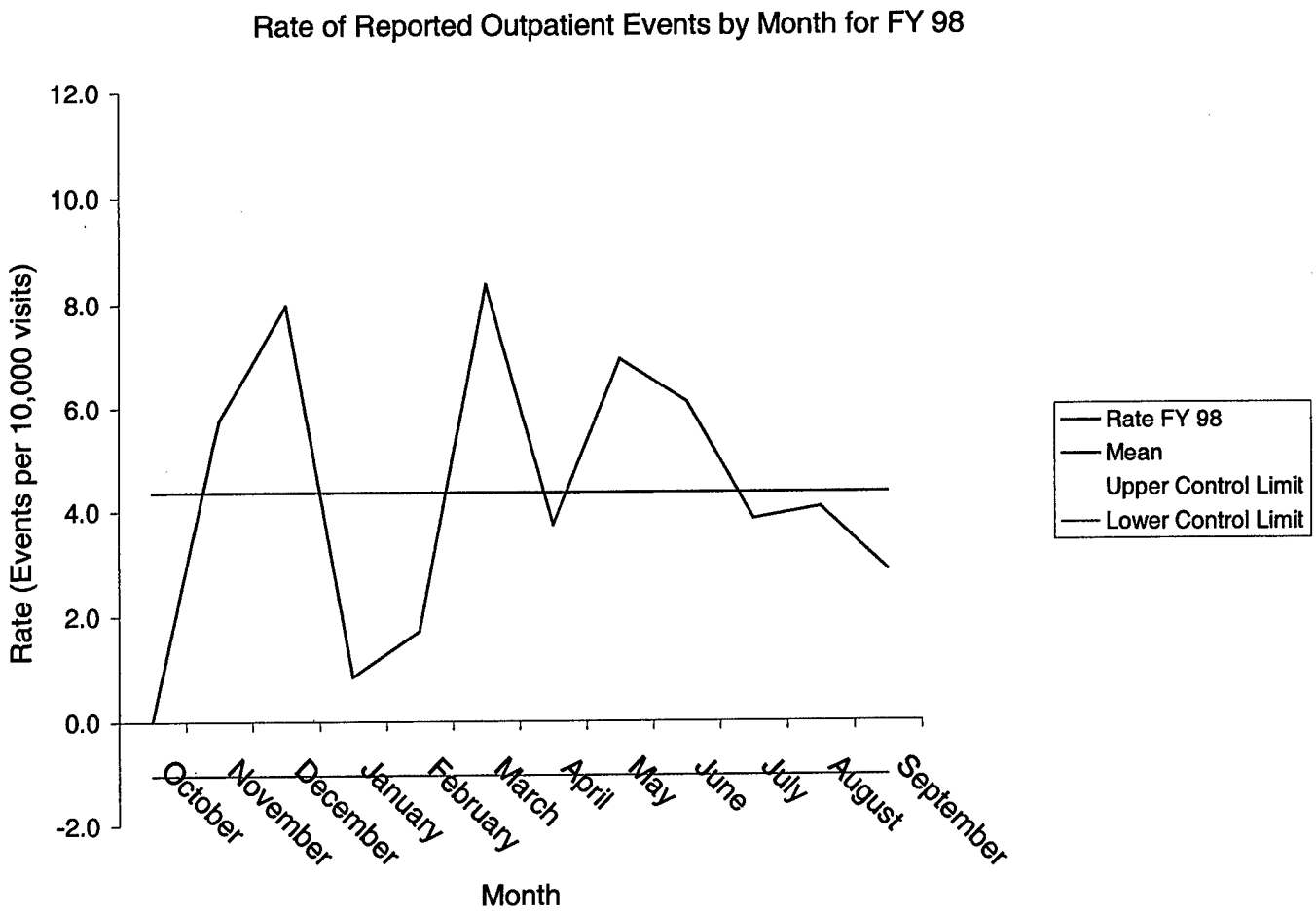
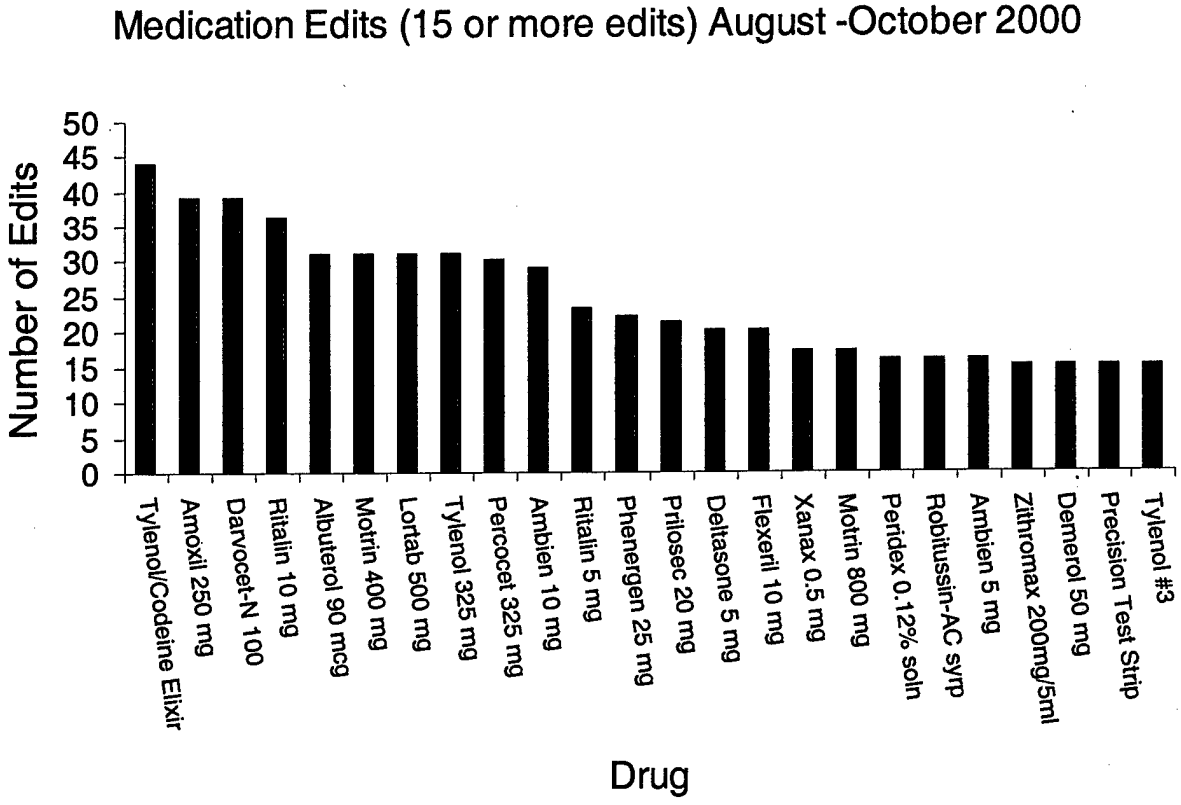

Rate of Reported Outpatient Events by Month for FY 98
12.0
10.0
8.0
6.0
4.0
2.0
0.0
-2.0
Rate (Events per 10,000 visits)
October
November
December
January
February
March
April
May
June
July
August
September
Month
Rate FY 98
Mean
Upper Control Limit
Lower Control Limit

Figure 8.


Medication Edits (15 or more edits) August -October 2000
Number of Edits
50
45
40
35
30
25
20
15
10
5
0
Tylenol/Codeine Elixir
Amoxil 250 mg
Darvocet-N 100
Ritalin 10 mg
Albuterol 90 mcg
Motrin 400 mg
Lortab 500 mg
Tylenol 325 mg
Percocet 325 mg
Ambien 10 mg
Ritalin 5 mg
Phenergen 25 mg
Prilosec 20 mg
Deltasone 5 mg
Flexeril 10 mg
Xanax 0.5 mg
Motrin 800 mg
Peridex 0.12% soln
Robitussin-AC syrp
Ambien 5 mg
Zithromax 200mg/5ml
Demerol 50 mg
Precision Test Strip
Tylenol #3
Drug